HOUSE OF COMMONS SESSION 1994–95

SCIENCE AND TECHNOLOGY COMMITTEE

HUMAN GENETICS

MINUTES OF EVIDENCE

Wednesday 8 February 1995

THE PATENT OFFICE, DTI
Mr Paul Hartnack, Comptroller-General, Mr Derek Wood and Mr Cedric Hoptroff

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Mr T W Roberts, Chairman, Biotechnology Committee, the Chartered Institute of Patent Agents and Mr Ian Armitage, Mewburn Ellis

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WEDNESDAY 8 FEBRUARY 1995

Members present:

Sir Giles Shaw, in the Chair

Mr Spencer Batiste
Dr Jeremy Bray
Mrs Anne Campbell
Cheryl Gillan
Dr Lynne Jones
Mr William Powell
Sir Trevor Skeet
Sir Gerard Vaughan
Dr Alan W Williams

Memorandum by the Department of Trade and Industry (30 January 1995)

GRANTING OF PATENTS—GENERAL SUMMARY

1. Patents in the United Kingdom may be granted under the 1977 Patents Act or the European Patent Convention (EPC). The latter was set up to provide a single procedure for obtaining patents effective in a number of European states. The European patent so granted, in each of the contracting states for which it is granted, has essentially the same effect as a national patent granted by the state. There are, at present, 17 contracting states under the Convention which is administered by the European Patent Office (EPO) in Munich.

PROCEDURE

2. The procedure for obtaining a patent is essentially the same whichever route is chosen. In outline, once a patent specification, containing a description of an invention and claims, which define the monopoly sought, is filed and the appropriate fees paid a search through the relevant databases of the "prior art" will be made to determine whether what the applicant is claiming is both novel and involves an inventive step. The applicant then receives a search report and the specification is published, as received, at 18 months after its priority date.

3. Substantive (full) examination of the application follows if requested by the applicant. During this stage the application is examined by a Patent Office examiner in order to ascertain whether it complies with all the pre-grant requirements of the Act or the EPC, as appropriate. Any objections are communicated, in writing, to the applicant who then has the opportunity of submitting amendments or arguments to overcome them. This process may be repeated until agreement is reached and the patent is subsequently granted. Publication of the granted patent then follows. There are procedures for settling disputes between the examiner and the applicant.

PATENT LAW

4. The law, both under the 1977 UK Patents Act and the European Patent Convention, is the same in all the essential aspects, particularly in respect of what may or may not be patented and the requirements placed upon the description and claims of the patent specification.

5. Patents may only be granted for inventions which are novel, involve an inventive step and are capable of industrial application.

6. For an invention to be novel it must not have been made available to the public, whether in the UK or elsewhere, in any way before the priority date of the application. In practice, availability will be established as a result of the examiner's search.

7. The criterion for deciding that an invention involves an inventive step is that the invention must not be obvious to a person skilled in the art having regard to what was known before the priority date of the application. This ensures that patents are not granted for minor, non-inventive modifications to previously known products or processes. An invention is judged to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

8. Certain things are excluded from patentability because they are not inventions. These include discoveries, aesthetic creations, computer programs and presentation of information. These exclusions are narrowly construed and do not extend, for example, to the technical application of a discovery or a computer

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program. Therapeutic, surgical and diagnostic methods practised on the human or animal body are also excluded, it being considered that they are not capable of industrial application.

9. The main requirements for the description of a patent application is that it should be clear enough and complete enough for the invention to be performed by a person skilled in the art. Likewise, the claims must be clear and in addition they must be supported by the description. Put another way, the monopoly covered by the claims must be fair in relation to what is disclosed in the description.

Biotechnology related patents

10. The criteria for granting patents described above apply to biotechnology related patents like any other patents.

11. However, both the 1977 UK Patents Act and the European Patent Convention exclude the granting of patents for animal and plant varieties and for essentially biological processes for the production of animals or plants. Thus inventions which relate to conventional animal and plant breeding are excluded from patentability but both the Act and the Convention make clear that micro-biological processes and the products of such processes are patentable thus allowing the patenting of genetically modified animals or plants as long as they are not claimed in the form of a variety. Plant varieties may be protected under the Plant varieties and Seeds Act 1964.

12. Concerns have been expressed about the use of genetic modification techniques on animals. However there are safeguards in place intended to protect animals, in particular there is the EC Directive on the use of animal experimentation (86/609 EEC) and the UK Animals (Scientific Procedures) Act 1986. These are the appropriate measures for safeguarding animal welfare and obtaining a patent in no way absolves the patent holder from complying with them.

13. A number of groups opposed to the production of genetically modified plants and animals have put pressure on the EPO and national patent offices to invoke the law that says that patents should not be granted for inventions the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour. They have reasoned that if patenting is prevented there is no encouragement to invest in the basic research and therefore the research stops. However, the morality provisions can only be applied in the clearest cases, since patent examiners do not have the necessary evidence on which to judge morality issues. The patent system is not the appropriate mechanism for tackling the question of what research should or should not be allowed.

14. The only other specific provision for patents involving the use or production of micro-organisms is that where the micro-organisms cannot be described in words they may be referred to by reference to their deposit in a culture collection. This enables a description which refers to the micro-organism to be regarded as sufficient.

Patenting of DNA Sequences

15. This is an area of considerable controversy which is reflected in the views of some who say that it should not be possible for sequences to be protected to others who say that protection is necessary in the light of the vast sums of money invested in research.

16. A brief search through the patent literature has shown that patents on human DNA sequences have been granted at least in the United Kingdom, Europe and the US. Examples are given in Annex A*.

17. It is of interest that a considerable number of patent applications have been filed for human DNA sequences but only a relatively small number have been granted with claims directed to the sequences *per se*. Of those granted a significant number would seem to be related to applications filed in the early days of the art, ie the early 1980s, although several US patents are more recent. Notwithstanding the situation in the US, this may be a reflection of the fact that, as the technology has become more widely understood and practice under the law has become more certain, much of the research leading to sequence information has come to be regarded as routine rather than inventive.

18. Neveretheless it cannot be said that patent offices will automatically regard a DNA sequence as lacking an inventive step. Even if a patent office examiner is inclined to that view, evidence will be sought from the applicant to decide the issue. If the evidence shows, for example, that for a particular sequence, when applying conventional techniques to locate it, there were unexpected difficulties the solution of which prolonged the work far beyond what might have been expected then it is possible that a patent might be granted. In other circumstances it may be that the applicant was the first to detect that a particular protein was the causal agent in a particular disease state in which case it is possible that a patent would be granted with claims to the protein by reference to its sequence and to the DNA sequence which expresses the protein.

* Not printed.

19. An important distinction needs to be made between the patenting of sequences whose function is known and those sequences arising out of the human genome project whose function is not known. The National Institute of Health in the US attempted recently to obtain patents for the latter in the face of international condemnation and subsequently withdrew their application which had received a preliminary rejection from the US Patent and Trade Mark Office. Lack of inventive step was only one of a number of objections raised against the sequence claims and it is still far from clear which objection(s) against claims of this type could be sustained.

20. It is a fact of patent examination that each case has to be treated on its merits and this is no less the situation in biotechnology than in other areas of technology. Parliament has laid down the principles and the examiner has to apply these to each case. Patent Office decisions may be challenged in the High Court – either on appeal if the patent is refused or in revocation proceedings if the patent is granted. Examiners rely on these court judgments in shaping their approach to future applications. If it is considered that the court decisions do not have the desired result, it is open to Parliament to amend the law. The Patent Office cannot do this; it has to apply the law as it stands.

Compulsory licences

21. Since the commencement of the Patents Act 1977 on 1 June 1978, two compulsory licences have been ordered in the United Kingdom. Neither was for a invention in the biotechnology field – one was for a method of honing surfaces and the other for a conveyor system.

22. In view of the small sample, it is not possible to generalise on whether compulsory licences tend to be ordered for new products or for ones reaching the end of their patents life. In the first of the case mentioned above, the licence was ordered in 1981 on a patent having an application date in 1966. In the second case, the licence was granted in 1990 on a patent having an application date in 1976.

23. In accordance with the Paris Convention for the Protection of Industrial Property, the Patents Act permits compulsory licences only on patents which have been in force for at least three years. Apart from that, the Government does not have a policy on the number of compulsory licences, or the age of the patents on which they are granted. Compulsory licences are only granted in response to specific applications, which have to be justified in quasi-judicial proceedings before the Patent Office on the basis of criteria laid down in the Patents Act.

24. The main grounds for the grant of a Compulsory licence are:

(a) failure to meet the demand in the UK on reasonable terms,

(b) meeting the demand in the UK by importation from outside the European Economic area,

(c) the efficient working of another patented invention which makes a substantial contribution to the art is prevented or hindered.

25. In future, the terms of any compulsory licences ordered will need to comply with the provisions of the GATT Agreement of Trade-Related Aspects of Intellectual Property Rights (Article 31).

Crown use

26. The main area where use of patents is authorised is in Ministry of Defence (MOD) contracts. By custom and practice, such authorisation is given in a Standard Contract Condition 32A, which authorises use of patents for the purposes of the contract. The rationale behind this is:—

(a) There should be minimal delay in fulfilling the contract

(b) Contractors are expected to exclude from their prices any contingency element to allow for the possibility of patent infringement claims. This results is a net saving to the MOD as only relatively few contracts result in claims for compensation for use of patents.

27. Other departments tend to authorise use of patents on a case-by-case basis. Generally, they reserve authorisation for cases where:—

(a) Patentees are unwilling or unable to meet an urgent demand

(b) A patentee is unable technically to deliver a product embodying the invention.

The availability of authorisation enables a Government department in effect to use first and settle later. This enables use to be made in situations where negotiation of a licence would take time and in situations where, under the Patents Act 1977, a compulsory licence would only be available three years after grant of the patent. If Crown Use did not exist, then in the very occasional problem or crisis situation it would be necessary to introduce emergency or other special legislation and this might itself delay necessary action in the relevant situation.

28. Department of Health use of the provisions has been circumspect and very occasional. However, the existence of the powers has helped to avoid a larger, but unknown, number of potential difficulties. Two examples serve to show their force. The first arose in the early 1960s when the Minister of Health invoked Crown Use to prevent Pfizer Ltd from using its patent rights to enforce excessive prices for the central purchase by the National Health Service (NHS) of oxytetracycline—which was critical to health care at the time. The action resulted in the Department obtaining its supplies of the product at one-tenth of the original Pfizer price, but the judge who dealt with the case emphasised the importance of exercising the provision only exceptionally and rarely.

29. The second example was more recent and involved action by a patentee against an NHS supplier for infringement of patent rights in respect of lithotripters in current use in hospitals. The Department's intervention and effective use of the threat of Crown Use ensured both prompt resolution and continuity of use of essential health care equipment in the NHS.

30. In 1986, the Home Office invoked Crown Use in order to be able to use genetic identification techniques in the forensic science service. The technique was still new, and, although there was an urgent operational need to use it, the patent holder was not yet in a position to supply. Subsequent negotiations led to an agreement for the future use of the technique in the forensic science service.

Draft EC Directive on the Legal Protection of Biotechnological Inventions.

31. The Council reached a Common Position on the Directive in February 1994 by a qualified majority. The Common Position included a number of provisions intended to go as far as the Council felt able to meet amendments adopted by the European Parliament at its first reading. The principal amendments were:

a. Patents should not be granted for the human body or parts of the body as such. A recital made it clear that "as such" when applied to things like genes, proteins or cells meant when they were present in the body and there was to be no ban on patenting of such material which had been isolated from the body.

b. Patents should not be granted for inventions which would cause suffering or physical handicaps to animals without substantial benefit to man or animals.

c. Farmers should have a limited right to save seed plants covered by a patent to sow on their own holding.

32. At second reading, the Parliament adopted three amendments to the recitals, one of which would have meant that material isolated from the human body would not be patentable on account of its human origin. Since the Council could not accept this amendment a Concilation Committee of the Parliament and the Council was convened. The Committee agreed a text of the recital according to which inventions including industrially applicable parts obtained from the human body by a technical process such that they are no longer ascribed to a specific individual cannot be excluded from patentability on account of the human origin of the parts. This text still has to be approved by the Council and the Parliament.

Examination of Witnesses

MR PAUL HARTNACK, Comptroller-General, MR DEREK WOOD and MR CEDRIC HOPTROFF, the Patent Office, examined.

Chairman

293. Thank you for coming, you are most welcome. Thank you for responding to our invitation to come and give oral evidence on behalf of the Patent Office on these rather important issues. The Committee are all named, as you see. Is there any statement that you want to make on anything before we start or may we commence the range of questions?

(*Mr Hartnack*) Mr Chairman, perhaps I may just say a few words.

294. Yes, please do.

(*Mr Hartnack*) I am the Comptroller-General of the Patent Office and Cedric Hoptroff is the Principal Examiner responsible for international relations and for general policy on patents and therefore on detail on that kind of issue I hope you will agree that he should answer, Mr Chairman. Derek Wood is the Principal Examiner responsible for the examining group of our specialists who look at patents in this area and therefore on patent practice perhaps you would allow him to answer, Mr Chairman.

295. Splendid, thank you very much, Mr Hartnack, for that information. If I may just start off, Mr Hartnack, I think probably to you yourself as head of the Patent Office, are most patents now filed at the European Patent Office rather than in the United Kingdom and, if not, is it possible to distinguish separately the type of patent application which does go to the European Patent Office and the type that will come to you?

(*Mr Hartnack*) The European Patent Office has been going since 1978. Over the last 15 years about 80 per cent of the overseas demand that we were taking from companies in, say, the United States, Japan and Australia in 1978 now goes to the European Patent

[**Chairman** *Cont*]
Office. We take 20 per cent by comparison. In terms of our domestic applications we process almost as many now as we did back in 1978, but about 20 per cent of the total finally end up in the European Patent Office. The distinction really is I think between smaller companies who really regard the United Kingdom as their market and larger companies particularly in this area of technology who see the world as their market and therefore would want to go to the European Patent Office for a single patent.

296. So the distinction, international, European Patent Office, and domestic, United Kingdom, seems to be broadly the case, except that there are some overlaps?
(*Mr Hartnack*) Yes, there are some overlaps, Mr Chairman. It really depends on the company's view, and most of our applications come from companies, of the commercial potential of their invention and the amount of money that they are prepared to pay to obtain patent protection round the world. In the pharmaceutical industry in terms of fundamental patent breakthroughs then one would expect the company to seek global protection. Even in the pharmaceutical area we do take applications both from UK companies and from overseas companies, although not very many, and the reasons for that may be to do with a view of a narrow market for the product or alternatively it may be a view of the quality of examination that we do in this country and therefore the likelihood of the applicants being able to enforce their rights in the courts.

Sir Gerard Vaughan

297. How do we stand in this country in relation to the American patent situation?
(*Mr Hartnack*) In terms of numbers, do you mean?

298. No, in terms of availability of getting patents. Do countries here have to go through us and the European Patent Office and the American Patent Office or do they go to America first because it is perhaps a wider patent? Is there a lot of conflict? It is a very broad question, I realise that. What is the situation?
(*Mr Hartnack*) Essentially patents are national ones and therefore you tend initially to seek rights in the country in which you work or live, so that Americans would seek initial rights in America and by and large British companies would seek initial rights in this country although they might go to the European Patent Office to get a bundle of European rights.

299. Could you, for example, have a development in this country which is not patented here yet but is patented in the States?
(*Mr Hartnack*) It is theoretically possible but unlikely, and it does depend on the residence of the inventor.

Cheryl Gillan

300. Are there any differences that could be simply highlighted between, say, the USA patent regime and the United Kingdom patent regime which would perhaps disadvantage UK companies or individuals?
(*Mr Hartnack*) There is a fundamental difference between the United States approach and our own approach. We in common with almost all other countries adopt a first to file system. The Americans adopt a first to invent system. This means that for practical purposes if you have lodged a patent application at our Office and sent us £25, then on the day that you lodge it you are given a date and for practical purposes if you are the first person to have lodged an application covering that technology on that date then you are deemed to be the inventor. In the United States it is possible to argue—even though you have published what you have invented—it is still possible to argue that you were the first to invent because that is the nature of their system.

Sir Trevor Skeet

301. But is that fair because you have one year's grace for the inventor, and should we not adopt that system here?
(*Mr Hartnack*) There are a lot of pros and cons in both directions, Mr Chairman. The first con in terms of the USA approach is that it is very expensive and time consuming to prove that you were the first. In the United Kingdom all you need, as I say, is a stamp from the Patent Office saying that your application was received on a particular date. In the United States you might have to prove by reference to research records that you were in fact the first person who invented, and that could involve lengthy court proceedings.

Mr Batiste

302. How often would a patent be likely to be accepted by one or other of your office or the European Patent Office and refused by the other?
(*Mr Hartnack*) It is pretty unlikely because our law is harmonised with that of the European Patent Office. The 1977 Patents Act incorporates provisions quite specifically that are in the European Patent Convention. We also, for example, have people like Mr Hoptroff or Mr Wood going from our Office to meetings at the European Patent Office on patent harmonisation, patent practice, patent classification and so on. At the highest level, after a patent has gone through to grant and then through opposition proceedings it is conceivable that a different view could be taken as between the European Patent Office's board of appeal and the United Kingdom courts, but in terms of the basic mechanisms for granting patents I think that it is unlikely.

303. So the law is the same, the practices are the same. Why did you then say in your opening comments that some people might choose the British over the European Patent Office on the grounds of the thoroughness of examination? Where would that difference in procedure creep in? Presumably it is on the basis that it would be more likely to be defensible in a court if they had gone to the Office that examined more thoroughly?
(*Mr Hartnack*) The issue in my mind is the issue of claims. The essence of a patent is that you describe what it is that you have invented in technical terms and you then make a number of claims. Now it is the process of, in effect, negotiation between the

[**Mr Batiste** *Cont*]
examiner and the applicant on the claim that very often leads either to a broad set of claims being granted or a relatively narrow set. An applicant might like a very broad set of claims because it gives him a broader monopoly, but on the other hand it is easier to attack that broad monopoly and therefore an applicant might like two bites in effect, one patent to grant broad claims and another one which is more restrictive and less likely to be attacked in court.

304. May I then come back to my original question which was, how does this difference in practice creep in between you and the European Patent Office where you might get broad claims granted in one and narrow claims granted in the other?

(*Mr Hartnack*) The practice is the same, but all examiners are human and all examiners have to act independently. They do not act under my direction on particular applications: they deal with applicants as individuals.

305. So if a claim is actually going into your office and in the European Patent Office at the same time would the respective examiners in the two officers liaise with each other in order to come up with a common result?

(*Mr Hartnack*) To my knowledge that has never happened. Derek Wood might like to say.

(*Mr Wood*) It never happens at all, Mr Chairman.

Dr Lynne Jones

306. May I just come in here on a quick point, Mr Chairman. Why do you need a separate British Patent Office, why could you not just be a decentralised office of the European Patent Office?

(*Mr Hartnack*) It is a question that has been put to me before, Mr Chairman!

Chairman

307. I am not a bit surprised!

(*Mr Hartnack*) Essentially the European Patent Office covering the companies in the single market deals with 17 countries, the whole of the European Community bar Finland, plus Switzerland plus Monaco and Liechtenstein. It offers one a patent for the whole of Europe and one has the advantage of dealing with a single bureaucracy rather than 17 bureaucracies if one goes through the European Patent Office. However, to get a typical bundle of European patents you would pay about 9,000 Deutschemarks, say £4,000. For a British patent, admittedly covering only one country, you would pay a mere £285, say 500 or 600 Deutschemarks, and if your market is in practice just the United Kingdom then you do not need the whole of Europe, and therefore our purpose is to support small and medium sized companies.

Sir Gerard Vaughan

308. Mr Hartnack, what you have been telling us sounds very reassuring and good news. Are you telling the Committee that the present system is satisfactory from your point of view and that it is reasonably efficient?

(*Mr Hartnack*) I believe so.

309. Really?

(*Mr Hartnack*) Yes.

310. You would not want to see it changed at all?

(*Mr Hartnack*) I believe that national offices being local and near the applicant are of particular value to small and medium sized firms.

Sir Gerard Vaughan: If you do have thoughts on this, maybe you could either write to us, if the chairman agrees, or come back later in your answers, because we have understood that you think all is well.

Dr Bray

311. The Patent Office does not exist in a vacuum; there is on the one hand the legislation of the Government and on the other hand the courts. The balance between these is presumably different in the United States and the United Kingdom and Europe. How influential is the United Kingdom Patent Office? Let me give you a specific issue, Mr Hartnack, on the very fraught issue of patenting genes which has been extensively debated by scientists and scientific bodies. I am not aware of any public contribution having been made by the UK Patent Office?

(*Mr Hartnack*) I am not sure that there has been a public contribution made by the European Patent Office either. They have held a forum but they have not entered into a general public debate on the matter. The way in which we try to operate is through consultation with the interests, and we have, for example, a Standing Advisory Committee on Intellectual Property which debates all issues relating to intellectual property and tries to take in interests as broad as the CBI, the patent and trademark agents, the small firms representatives and so on, so we operate through these consultative procedures rather than through public debate.

312. But did the Patent Office play any part at all in the discussions between the Medical Research Council and the national institute?

(*Mr Hartnack*) I attended a meeting very early on in that process where the Medical Research Council and other main players on that issue were present and my opinion was sought, yes.

Mrs Campbell

313. I should like to ask you about something that you put in your memorandum. You made it quite clear there that the patent examination relies upon a search of the Patent Office database. I wonder whether you can explain to us how the database is maintained and also what technical qualifications patent examiners have to enable them to judge the novelty and utility of a patent application's claims on the basis of the material that they recover from the database? Have they got the expertise to reject claims which are wider than the basic invention warrants?

(*Mr Hartnack*) I certainly believe so, Mr Chairman, but perhaps I could ask the gentleman responsible for it to answer, Mr Wood.

(*Mr Wood*) Mr Chairman, may we take the second question first about the qualifications of patent examiners. Some of them will have a degree in a relevant science and in this particular area of

[**Mrs Campbell** *Cont*]
biotechnology there is a fair chance that they will have PhDs so on the technical side they are well equipped to deal with the matters that they are reading about in the specifications. As far as the databases are concerned, they are constructed from our own paper files which are patent specifications granted here, in America, Europe and under the PCT, which is effectively the worldwide patent system. In this particular area, Mr Chairman, we rely a lot on commercial on line databases and the searching for the relevant matter is very effective in this area. It is very easy to select the appropriate key words so that on line databases become very viable in this area providing us with probably more than we get from our own paper files; they are giving us access to the many journals where this information is published.

Sir Trevor Skeet

314. Mr Chairman, I wonder whether I can just pursue this a little. I understand that there is a disagreement between the Council and Parliament over a legal protection of biological inventions and a joint text was agreed on 23 January of this year. How is that likely to go and how will it be resolved?

(*Mr Hartnack*) Mr Chairman, Mr Hoptroff actually attended most of the meetings so perhaps he might respond on that.

(*Mr Hoptroff*) Mr Chairman, the problems all turned on the question of the extent to which material that had been taken from the human body could be patentable. The Council's common position on this Directive would have enabled the patenting of small parts of the human body provided that they were removed from the body and not part of it. The Parliament, when they considered the Council's common position, adopted an amendment which would have changed the meaning—

315. That is Amendment No 3?

(*Mr Hoptroff*) Yes—of the Directive at that point so that parts of the human body even when they had been isolated would no longer be patentable. The Conciliation Committee produced a compromise text which effectively says that as far as inventions including industrially applicable parts of the human body which have been removed by some sort of technical process so that they are no longer ascribable to a particular individual are concerned, there is no reason why those should not be patented.

316. Is that acceptable to the pharmaceutical companies because if they are going to be disadvantaged they will leave Europe and go elsewhere?

(*Mr Hoptroff*) We have kept in constant touch with the pharmaceutical companies and the biotechnology industry generally over this, Mr Chairman, and they are satisfied that this is a text that they can live with.

Chairman

317. They can live with it?

(*Mr Hoptroff*) Yes, Mr Chairman.

Chairman: Good.

Cheryl Gillan

318. All the disease gene discoveries are really a combination of large and often international collaboration between patients and doctors and scientists and many of them absorb large quantities of public funds and money. Can you therefore tell us whether you think it is right that a patent should be granted only to the individual who puts in the last piece of the jigsaw?

(*Mr Hartnack*) There is obviously an issue of a return to the taxpayer,Mr Chairman. The difficulty that I perceive is that although tens of millions are spent round the world on mapping the genome those tens of millions are a relatively small amount of money compared with the amount of money that is spent by pharmaceutical companies on R and D. It is also true to say, I think, that this country would gain no particular benefit from taking a particular line on return to the public purse because France spends as much as we do and the Americans I suspect spend a lot more so that there is nothing much to be gained. Therefore, it seems to me that the second part of the argument is that since the UK patent system exists to promote innovation and to promote competitiveness in industry, and I would say therefore primarily British industry, it is a good thing that patents are possible in this general area. The extent to which they should be allowed is one which we determine in terms of the current law and by reference not only to the law in this country but to jurisprudence overseas and what other EC Member States are doing and by reference to what the courts do and, if I may say so, above all what Parliament says, so that if Parliament were to legislate we would change.

319. Following on from that, and referring to your written evidence to the Committee, particularly on the development of patent law, you said that if it is considered that the court decisions do not have the desirable result then it is open to Parliament to amend the law, but that the Patent Office cannot do this and it has to apply the law as it stands. Do you personally think that there is any part of the law at this stage that needs amending?

(*Mr Hartnack*) No, I am perfectly satisfied with the law.

320. Perfectly satisfied?

(*Mr Hartnack*) Yes.

Chairman: What a benign organisation you are!

Cheryl Gillan

321. It is nice to meet a satisfied customer!

(*Mr Hartnack*) Mr Chairman, since Sir Gerard Vaughan asked a question about whether there was anything that we would change, I might mention that there is a lacuna I think in the European system that comes in both the United Kingdom and the European Patent Office and that is that if somebody applies to the European Patent Office for a patent and the patent is finally granted, then the UK courts can form a view as to whether that position is correct. If on the other hand somebody applies to the European Patent Office and the patent is not granted, then that is the end of the matter. Therefore, it is important that this country accedes, putting it shortly, to the Community patent which will bridge

[**Cheryl Gillan** *Cont*]
that gap: so it is in that sort of area that there may be a problem although it has not in fact caused major difficulties so far.

Chairman

322. May I raise point here. In the main commercial development the vast majority of R and D spending is downstream, is it not? Is there not a prima facie case for allowing patenting at the discovery stage?

(*Mr Hartnack*) Mr Chairman, the difficulty I think with patenting of gene sequences of unknown utility—if I have understood your question—is that the state is after all giving people a monopoly and to give people a monopoly to do one knows not what is a difficult concept.

323. So you would require to have a demonstration of in what way the discovery was to be, as it were, marketed?

(*Mr Hartnack*) The system is about industrial application and that is what the claims attached to a patent are about.

Sir Trevor Skeet

324. Yes, but, Mr Hartnack, you say it is capable of industrial application under the 1977 Act. Anything may be capable but would it not be better to amend that and say that it is of use because in many cases it could not be proved? In this particular field in which we are interested it might not be proved to be of any use, it could not be proved. Is this not a stumbling block?

(*Mr Hartnack*) Frankly, Mr Chairman, I do not see it as a stumbling block because one could take a map of the entire genome and say, we think that this might be of use, and the first person to have got £25 into the front door of the Patent Office wins. I am not trying to be impertinent, but you see the problem. We do have to try and establish what is a reasonable monopoly and that is in effect the negotiation that takes place between the examiner and the applicant. If we are too generous, then what happens is that the courts overturn us and then if Parliament is not happy with that Parliament changes the law, so we have a nice circle.

Mr Batiste

325. I should like to go back to the chairman's question and your answer to it which I could not quite follow. You said that you could not see the case for patenting the discovery of a gene sequence of unknown function—you discovered the gene but you did not know what its function was. I cannot see why there should be any difference between that and knowing what the function was because you are still just discovering something that is already existing. Surely the borderline should be after that when you are doing something inventive. Is that not where the borderline should be? It is not a question of whether you know what the gene sequence does or does not do; it is whether you do anything to it?

(*Mr Hartnack*) I am sorry, that is effectively what I believe to be true. That is my position.

Chairman

326. The gene itself . . .

(*Mr Hartnack*) It needs to be established what there is that is capable of industrial application.

Mr Powell

327. I understand that substantive or full examination of an application is only done at the request of an applicant. Why would an applicant wish to have a full examination of the application? Can you also help about how this would be carried out in the European Patent Office regime? Is it done by the national states or is it done by the European Patent Office itself?

(*Mr Hartnack*) Mr Chairman, obtaining a patent in this country and, indeed, in the European Patent Office is subject to the same process. First, you send in an application to obtain a priority date as I have described. That just gives you a date saying that you were then first. Having done that you have a period of time in which to decide what to do next. You might want to carry on, you might decide that in fact there is no market for what you have invented and therefore you just want to drop it. But if you decide to continue, the next stage is to have a search of the prior art and that will be done in this country by one of Mr Wood's examiners and at the European Patent Office it will be done by an examiner in their search facility in The Hague. What you are given essentially is a list of previously granted patents which come close to your invention. It might give one which knocks out your invention because it has been invented before. But suppose for the sake of argument that all you get is a list of patents that come close, you then have to decide whether you want to proceed to the final stage of substantive examination of your application, and in that substantive examination your claims for what it is that is inventive about it will be the subject of the substantive examination. Mr Chairman, I do not know whether Derek Wood who does this every day wants to add anything to that.

Chairman

328. Yes, Mr Wood?

(*Mr Wood*) Mr Chairman, I would say that one of the effects of our search of course is that there may be an overlap and the applicant then has to make an assessment of whether there is in fact enough left to continue with the application or not. It is in fact fairly infrequent that we get what examiners call a knock out citation. But often there is an overlap between it and what has been done before and it is in this area that an applicant will have to make up his mind whether there is enough left to proceed with.

329. And that would be all for the £235?

(*Mr Hartnack*) It is £25 for the application plus £130 for the search and £130 for the substantive examination.

Sir Gerard Vaughan

330. You said just now that it might be one that is knocked out. Could that come from the States? What happens if you do not agree? All is not harmony all the time surely about what should be patented in this country and what should be patented elsewhere?

(*Mr Hartnack*) You can only have a patent for something that is novel and capable of industrial application.

331. By industrial you mean commercial?

(*Mr Hartnack*) Yes, capable of industrial application. Novelty is global. If it has ever been published before—it does not necessarily have to be a patent—we cannot give an applicant a patent.

Mr Batiste

332. You said that you are governed by the law and the law will be determined ultimately by statutes, by judgments that will be passed down by the courts. Presumably you have a structure in house for identifying judgments of relevance and for disseminating them among the staff and ensuring that there is a uniformity of observance? Is there such a system in place?

(*Mr Hartnack*) Yes, we have a very sophisticated system.

333. As long as there is, I am sure that we are happy with that. Let us then take it one stage further. Our law is part ours, part harmonised European on patents, so presumably the decisions of courts in other countries which are also harmonised to the European legislation will have some persuasive influence on you too, would that be fair?

(*Mr Hartnack*) We monitor what happens in other courts. I understand that UK judges also take account of what is done in the European courts and, indeed, last year we hosted a conference of patent judges from round Europe and America and the Japanese and—

334. These were at the national level rather than the European level?

(*Mr Hartnack*) And European, all together.

Dr Lynne Jones

335. May I go back to the issue of the patenting of genes, Mr Chairman. I understand the point about industrial application, but why should the gene be able to be patented rather than either the actual application itself or perhaps the method or the step to isolate and identify the gene? Why not the immediate steps before being patentable, the immediate steps after, but why patent something which is not actually an invention, it is just discovering what is actually there all the time?

(*Mr Hartnack*) Well, if it were just a discovery, we could not patent it. Perhaps Derek Wood could come in here who is, as I say, a practitioner.

(*Mr Wood*) Discovery in a patent sense is in the sense as it were of falling over something that occurs in nature so it is, of fairly limited definition. I think that that is worth bearing in mind when we look at the patenting of genes, Mr Chairman. As to whether someone would get a patent on a gene or not, this depends very often on what is k nown about the gene at the very beginning. It may be that someone is researching in an area where they suspect a particular disease is caused by a malfunctioning gene but that is about the limit of their knowledge, so the actual work which identifies that gene and then works that gene up into a marketable product as a package is granted a patent in that area. However, it very much depends on what is known about the gene in the first place, Mr Chairman. If a lot is known about the gene, where it is, what it does, then the chances of getting a patent on the gene sequence really is tending towards zero.

336. But why should it be patentable? Why not the process of identifying it and the use itself, but why the gene itself? Looking at the list of genes that have been patentable why should they be patentable, why not the process associated with their discovery or use but not the actual identification?

(*Mr Wood*) The actual value of a patent for a process is in fact quite limited so applicants will want to go for the broadest that they can get and this will depend on the amount of inventive effort that they have involved in arriving at the gene of interest.

Chairman

337. So the inventive effort in relation to the discovery is as much patentable as the inventive effort in doing something about it?

(*Mr Wood*) Indeed, Mr Chairman.

Dr Lynne Jones

338. But does this not inhibit further research on an application of a different nature on that gene in that one body has got a patent?

(*Mr Wood*) It does not necessarily inhibit. What it might mean is that somebody coming later and building on the information that somebody has already put into the public domain by actually finding that gene owes something to the original inventor.

339. But that would be the process, not the actual gene itself. They could come and do something that is completely different with that gene.

(*Mr Wood*) Yes, they could do something different, use it in a different way, and then there might be a patentable invention.

340. But the gene would be patented and they would have to pay royalty even though none of the new use of it owed anything to the research that had taken place?

(*Mr Wood*) They may well have to do that. That is not very different from what is commonly the case in the chemical area in general.

Dr Bray

341. Is not an invention something that was not there before whereas a discovery is something that was there before and you have found out about it? Judgments about how much effort, brilliance or competence was involved in the process is neither here nor there in the difference between discovery and invention. It is that core discovery of something that was there before.

[**Dr Bray** *Cont*]

(*Mr Wood*) That is not the way that patent law has developed. Back in the early sixties this whole issue arose in the light of microorganisms. Discovering, if you like, a microorganism in what might be a soil sample, almost from that point on has been regarded —the isolation and making it available when really nobody knew of its actual existence —as patentable subject matter. What has happened over the period of time is that as we have come to gene sequences we have built on those precedents of the past.

342. But does that not open the door wide because science generally is a highly ingenious process and anything that has been discovered is in your sense an invention?

(*Mr Wood*) No, there may be instances where it is not invention. It depends what we know, as I said earlier on, about the gene of concern. There are a lot of genes in the genome that (a) nobody knows exist at the moment (b) certainly nobody knows the function of them, and it is in this area that there is input of intellectual effort in actually isolating a gene, which in fact once it is isolated is not necessarily the same.

Mr Batiste

343. I am sorry, could you say that again?

(*Mr Wood*) When the gene is isolated from the genome it is not necessarily the same as it exists in nature.

Dr Bray: But in what respect?

Chairman

344. No one has done anything to it?

(*Mr Wood*) Because usually what you have got when you isolate from the genome is that you have got a copy of the working part of the gene where what is known as introns have actually been cut out. The introns are pieces of DNA which exist in the genome but they do not exist in the working copy of the genome so that the actual sequence that you isolate in fact is not the same as the sequence which exists.

Dr Williams

345. Perhaps I can just come in here, Mr Chairman, because that is very difficult to identify and it is a very grey area. Twenty years ago, ten years ago, it was very difficult to identify genes and to identify their functions. By today and in ten years time it becomes easier and easier and maybe in ten years time there will be some genes that it will be very difficult still to find functions for. Placing the Patent Office in the place of judgment as to what did take a lot of inventive effort and what did not take so much inventive effort is something that is totally grey?

(*Mr Wood*) It is a difficult area and sometimes it is a grey area, Mr Chairman, but we are making those decisions against the background of what is known in the prior art. That is the function of our service and part of the argument that will go on in the substantive examination that we have been talking about earlier will in fact be a negotiation as it were between the office and the applicant as to what is practical and what is not practical so that we are not in fact making these decisions in vacuo but we are making them against what is known in the prior art.

(*Mr Hartnack*) Mr Chairman, if I may I should just like to try to give a slightly different answer, and perhaps to give a gloss to it, in relation to what Dr Bray said and Dr Williams said. At a philosophical level one could take the view that anything to do with genetics should not be patentable—it is a discovery. But we are where we are. The purpose of the patent is to foster innovation, encourage new things to come to the market place, to do that to foster the competitiveness of British industry. Now when this work started 30 years ago what was done in genetics was highly novel and therefore concerned very broad things. We are now 25 years on and I would have thought that anyone who attempted to patent a gene sequence of unknown utility today would not stand much chance.

346. We could have a clear dividing line here between discovery and invention if you define the gene sequence as being simply part of discovering the truth and its function also as part of that, but when you come to developing diagnostic tests or gene therapy treatment, those are applications, it is inventive, they can be improved on, there is no monopoly there, but in terms of the gene sequence and its function you just uncover the truth, as it were, and those parts should not be patentable. There will not be a clear dividing line there, will there?

(*Mr Hartnack*) One could have taken that position a quarter of a century ago. My response is that patents have been granted round the world to companies and to individuals who expended effort on research a quarter of a century ago, 20 years ago, ten years ago, and what they were doing at that time was highly novel.

Dr Bray

347. Patents expire.

(*Mr Hartnack*) Some of them have not. One has just gone in the Court of Appeal—1980 is a sort of benchmark there. In relation to where we are today obviously, as I have said in answer to previous questions, Parliament will take a position on this, but what I am saying is that gene sequences of unknown utility I would have thought are highly unlikely to be patentable today.

Dr Lynne Jones

348. You said that Parliament could take an alternative view and in fact the European Parliament has taken an alternative view. What I should like to explore is what would be the practical difficulties of changing the system. We understand how it has evolved. But if you had a system which said that genetic information was unpatentable information discovering what was there already therefore the only patentable discoveries or patentable inventions are the process whereby the gene is identified or the process by which it is turned into some use. Why can we not change the system?

(*Mr Hartnack*) I think that the practical implications of a fundamental change in the system like that are that the people who spend really serious

[Dr Lynne Jones *Cont*]
money on research, and that means the private sector companies essentially, would find that they were less likely to get a return on that research than under the present system.

349. But many companies think otherwise and are in fact campaigning against that—Merck, the biggest pharmaceutical company?
(*Mr Hartnack*) Well, there is an issue of market power alongside of that. All that I am saying to try to illustrate the point, Mr Chairman, is that of the patent applications that I get in my Office—and the same is true in Germany and much the same is true in the States—1 per cent comes from academics, 70 per cent from industry and the rest comes from private inventors—who are not usually in this field—so most of the patent applications are in fact coming from industry.
Dr Williams: If I may say so, Mr Chairman, most of this work is being done by scientists, not by those companies, and yet the position that you seem to be taking, Mr Hartnack, is that it is in the interests of the companies rather than of the scientists. You are taking a commercial angle depending what may be in terms of industrial application possible, but really, so far as I can understand at this stage the opinion of scientists, what is wanted is freedom of information, not patenting of gene sequences and their functions. The tests?—fine, let those be patented—but it seems to me that the law as it now stands perhaps has been one that has developed on the basis of commercial application and in the interests of companies rather than on the basis of good science when in fact over 90 per cent of the work is done by good scientists.

Chairman

350. That of course raises your original function, does it not?
(*Mr Hartnack*) Frankly, Mr Chairman, it just is not so. As I say, 1 per cent of patent applications come from scientists.

Dr Williams

351. But they do not want to patent their knowledge!
(*Mr Hartnack*) It may be they are not motivated to do so, but I am simply describing the system, Mr Chairman.

Dr Bray

352. The merits or value of scientific research is not proportional to the number of patents.
(*Mr Hartnack*) I am not arguing that.

353. You are!
(*Mr Hartnack*) I am saying, as the custodian of the Patent Office that most of our applicant cases come from industry, industry uses the system which is designed to foster innovation, bringing things to the market and competitiveness, and therefore where we are in terms of that system is something that I have to put to you, which I have tried to do. Now there are obviously moral, philosophical, arguments that one could bring into play—frankly, they are not for me.
Chairman: I think that that is a very fair statement of your position under the law as it presently exists, and we have taken note of what you say, Mr Hartnack.

Mrs Campbell

354. Let us get away from the moral and philosophical argument for the moment because that is not what I am asking. Do you think that in the approach that we have taken there is some danger that you actually diminish the possibility of scientific discovery and scientific research?
(*Mr Hartnack*) Scientific discovery and scientific research are funded in one of two ways. Either they are funded by government which will have all sorts of reasons why it would wish to fund R and D or by Industry, which I suspect will have a very powerful commercial motive.

355. But I am not talking about the funding; I am talking about the possibility of doing work on something that has been patented as an industrial application.
(*Mr Hartnack*) If it has been patented the chances are that one is talking about further work that would be done to take it downstream even closer to the market. When I said only 1 per cent of applications are from academics it is because academics tend to be interested in pure science. Now as to what they do, very often it gets developed by industry. What industry then does gets further developed. What we are addressing is the possibility that something genetic is given a patent and what I am postulating is that further work on something after it has been patented is likely to be done by industry rather than by academics because academics would have moved on to something else.

Mr Batiste

356. I wonder if you would help me to clear my mind on exactly where the borderline is, leaving the wider considerations out which you say are not for you. You have said quite clearly that a gene of unknown utility is unlikely to be patentable. That is one clear position. At the other end it is a very clear position that anything that is done that will alter the gene or the methodologies for discovering the function of genes, anything in that sort of area, clearly would be patentable. The area of difference or uncertainty is the sheer process itself of discovering what the function of the gene is, and in that context you have described it as a measurement of the inventive effort that goes into it. Now in just the same way as today you would now think it unlikely that a gene of unknown utility could be patented, how would you measure what further inventive effort is needed before you would be saying that merely running a computer for X hours and spending whatever money is necessary to identify what a gene does is no longer really inventive? How do you measure that and how far off are we getting to that point?
(*Mr Hartnack*) Mr Chairman, I would like Derek Wood to give his opinion because he is in fact in the hot seat, but I have to say that it depends on each individual case in my opinion. Each individual case

[**Mr Batiste** *Cont*]
will be different from the one before it and the one after it. In looking at each individual case we have to have regard to practice round the world, what is being granted and what is not, the views of judges in particular in this country as to what should be granted and what should not be granted and to what Parliament says, so that you have in effect a circular system in this country and one which is global, and within that we try to slot each application in a moving situation where, as I said, 25 years ago you had one situation and today it is different and ten years hence it will be different again. Perhaps Derek Wood has something to add here.

(*Mr Wood*) Mr Chairman, the measurement as far as we can do it is done against what is already known in that particular art itself.

357. If, for example, very sophisticated computer programmes are designed to try to eliminate alternatives and to come out with what the probable function of the gene is, quite clearly there may or may not be protections—if the programme is patented there would be and if it is not there would not be—and it may not in itself be directly patentable, but once that sort of programme is running the application of the programme itself would then eliminate the inventive element because there would be a known technology for discovering the function of a gene and once you have reached that point you would move forward and say that the mere discovery of the function of the gene would not be patentable.

(*Mr Hartnack*) It might be worth bringing in one of the concepts of the patent which is that whatever the applicant is seeking a patent for must not be obvious to someone who is skilled in the art. Now clearly as science moves on more people become skilled in the art and therefore obviousness is the test in this area; so that what is obvious today was certainly not obvious in 1980. That is the judgment that the examiner has to make.

Chairman

358. What would be the average life of a patent in this area?

(*Mr Hartnack*) In this area, Mr Chairman, it depends on the amount of money that it is making. The system is about money. The average life of a patent is about 11.2-11.3 years. If they are making a lot of money they could last for 20 years; and if they were in the pharmaceutical area they might be eligible for a supplementary protection certificate.

Dr Bray

359. Your limitation of consideration to what is of commercial and industrial interest, excluding the philosophical and moral considerations, is in danger of including also logic and equity. For example, you argued, Mr Wood, that the presence of introns in some way differentiated the gene under consideration from the gene as it is patented. It is rather like saying that the railway timetable which has got a fly stuck in the middle of it is different from a pristine railway timetable without the fly. Is that not totally irrelevant?

(*Mr Hartnack*) What we are trying to do is to take account. It is our practice—it is the practice of all patent offices—to tend to err in favour of the applicant and we do that because, as I say, our function is to try to foster innovation. Now in erring in favour of the applicant we know that all of our decisions are challengeable in the courts. We also know that in almost any area of technology there will be competitors so if we were to err in favour of one pharmaceutical company in this country and the competitors of that company thought that we had gone too far, then they would challenge that decision in the courts; so indeed would other interests, people who—

360. Yes, but with respect an individual scientist on a £20,000 research programme who is grossly overspent already could not possibly afford to contest a patent filed by some pharmaceutical company which is knocking out his whole area of research.

(*Mr Hartnack*) If that scientist worked for a university presumably he would be being funded by the Medical Research Council, and if the Medical Research Council felt that its ability to pursue fundamental research in this country was being prejudiced, then the Medical Research Council would take up the case and other interests would take up cases.

361. But you are really making it extremely difficult for us in wanting to provide the maximum possible incentive for the pharmaceutical industry to find effective applications of genetic concern to define their interest in such a way that it does not unduly limit the pursuit of the research phase. Do you not have an obligation also, not to the person who applies for the patent but the person who would otherwise use the information if it were not patented?

(*Mr Hartnack*) That is not the way that Parliament has seen it hitherto, and I can only repeat that the basic mapping of the genome is largely funded by government in this country, so as far as the fundamental science is concerned government has taken that on precisely because it is, if I may use the term, blue skies science. What the Patent Office addresses itself to is science in this area where as of today we are not talking about genetic sequences of unknown utility. Therefore it is much more applied science and less likely.

Chairman: For commercial purposes.

Mr Batiste

362. You have already said that in your view things having developed to the point that they are now a gene of unknown utility is not patentable. Would it be possible subject to protection from the law of copyright?

(*Mr Hartnack*) I have pondered that at great length. The difficulty is that even if it were —and the 1988 Act talked about copyright protection for tables or compilations so I suppose from that point of view it might be regarded as complementary, but that does not really help because no one would want actually to print copies of the genome and sell them to someone. You see the difficulty?

Mr Batiste: Yes.

Dr Bray

363. The examples that you have given in your Annex A of DNA sequences for which patents have been granted as amateur reading all seem to relate to the function of the gene only. They do more than just describe the DNA code; they describe the function. But they do not describe the application, they do not describe the utility. How did these satisfy the requirement of utility?

(*Mr Wood*) Mr Chairman, the utility area is a difficult one. As has already been said, an invention has to be susceptible of industrial application and in many respects that has not been tested in this country as to what that actually means, but that is not the be all and end all of the problem, as it were. If you go through some of those specifications you will see at least in some of them that there is at least the anticipation of working them up into therapeutic compositions and a certain amount of detail is given about the potential use of these gene products.

364. Is it not enough to say that it is therapeutic; you have to say in what particular respect it could be used therapeutically.

(*Mr Wood*) In terms of the description you do not always need a great deal of information about the potential use, and to go back to these, Mr Chairman, some of these are quite early ones in the whole area of genetic engineering. Some of the early 1980 ones, as I think that we said in our memorandum, may well not have been granted today for a variety of reasons, because the art has moved on, and it may well be that by present standards we may well judge that some of these would not be patented.

365. None of these are more than ten years old.

(*Mr Wood*) That covers a large part of the time in which biotechnology and genetic engineering has been a viable industry.

Dr Williams

366. If I could just come in here, Mr Chairman, I notice that here the last date is 1986 with nothing since but the three American ones are 1992, 1993 and 1994. Does that mean that we are now falling out of line and we are taking a much more academic view of things as opposed to the approach in America?

(*Mr Wood*) These are only a representative of those we found where sequences had been granted. It is probably true to say that in America they do have a fairly liberal regime there.

Chairman: We will be asking something about that shortly.

Sir Trevor Skeet

367. The Act obliges you to call for very strict conditions. One of them is contained in section 1(3) which says that a patent shall not be granted for an invention excepted to encourage among other things immoral or antisocial behaviour. It is coming up to 20 years. You now have biotechnology in a big way. What we are finding of course is an ethical approach to this. Should the Patent Office be involved in a judgment on these matters or how do you interpret it?

(*Mr Hartnack*) It would follow from what I said before, Mr Chairman, that I rely heavily on case law and on what the courts say. In my life time parliament has legislated to make various things which were illegal legal. What we are talking about here is really quite subjective morality. I would take it upon myself to say to my examining colleagues that an instrument of torture should not be patented. But in an area like this my hope would be that they would err on the side of the applicant and allow the courts then to take a view, and then Parliament would take a view on what the courts had said about what we had done and, if Parliament so wished, it could change the law.

Chairman

368. Perhaps I can just ask you this question on that because you have referred to the role that the courts play in defining this. How many such cases on average come before the courts where your patent has been found "invalid"?

(*Mr Hartnack*) On moral grounds or on general grounds?

369. On general grounds?

(*Mr Hartnack*) It is very rare, one or two.

370. Broadly the courts are supportive of your interpretation of how your remit should be exercised within the law?

(*Mr Hartnack*) We take a fairly tight view in the British office.

Sir Trevor Skeet

371. Yes, but when you are concerned with the major balance in section 1 should you be so concerned with the ethical approach which this particular biotechnology is forcing upon you? We are being asked now to consider whether we should impose restrictions from Parliament and whether we should put this in an Act of Parliament. Are you not primarily an administrative office who will grant monopolies for a temporary period in return for something which is given by the companies?

(*Mr Hartnack*) That is very much my view, Sir Trevor, and it is also my view, if I may say so, that there are other pieces of legislation that cover moral issues—cruelty to animals or whatever; they are not enshrined in the patents legislation, they are enshrined in other legislation.

Mr Powell

372. In answer to the chairman you emphasised that your decisions have only been overturned by the courts in one or two cases—very rare, you said. It is important to stress, is it not, that the courts are not rubber stamping your decisions? One of the reasons why your decision are so rarely overturned is that you pay such scrupulous attention to what the courts say when you are handling applications before you, so that it is a two-way process, not merely the courts accepting the judgments that you have made because you have made them?

(*Mr Hartnack*) I certainly do not believe that that is the case. We follow very carefully; we have—I did

[**Mr Powell** *Cont*]
not give the details—a very complex /system of monitoring what goes on both in the UK courts and in Europe and round the world.

Dr Lynne Jones

373. Can you explain the arrangements for royalty charges? Who decides this? A licence is granted by the person who holds the patent. Are there any limits to the amount that they can charge for that licence?

(*Mr Hartnack*) Royalties is a very complex subject, Mr Chairman.

Chairman

374. Mr Hoptroff, have a go?

(*Mr Hoptroff*) Mr Chairman, basically it is for the parties to negotiate royalties between themselves, and there is no limitation on what royalty can be charged. There are, though, in the Patents Act provisions for compulsory licences in certain circumstances where patent has been abused. If the market in this country is not being met it is possible for a compulsory licence to be given to someone. That is done by the person who wants the licence coming to the Patent Office and asking us to settle the terms of the licence. Part of the terms then would be setting the royalty level and we would be governed in doing that by precedents in similar sorts of cases in the past.

Dr Lynne Jones

375. And would that take account, for example, of the cost to the patent holder of achieving patenting of their invention?

(*Mr Hoptroff*) Yes, the level of royalties would be designed to give fair return to the patent holder for the loss of his monopoly.

376. So basically two people can agree on the royalty charges and they come to you as an arbiter of last resort?

(*Mr Hoptroff*) Yes. I would just stress, Mr Chairman, that this is only where the patent holder is abusing the patent in some way. It is not a right for anyone to come along and demand a licence on any patent.

377. So somebody could have a patent on something that had not cost him very much but it was a real dynamite patent worth a lot of money and because there was a real demand the market would accept very high royalties, is that correct?

(*Mr Hoptroff*) The market might very well set high royalties, yes.

Chairman: Now our final question.

Dr Bray

378. Does the GATT agreement on trade related aspects of intellectual property rights have implications in respect of compulsory licences?

(*Mr Hartnack*) This again is an area where Cedric Hoptroff could best respond.

(*Mr Hoptroff*) The effect of the agreement on the laws in this country is likely to be fairly limited. It is going mainly to affect the law in developing countries where the systems of intellectual property protection are not quite so well developed as they are here.

379. Including China?

(*Mr Hoptroff*) Yes, although at the moment it is not quite clear whether or when China will come into the World Trade Organisation. But if they do that will be a considerable benefit.

380. Is the work of that organisation going to become a major forum for international negotiations on patent matters, particularly in the (?defence?) field?

(*Mr Hoptroff*) At the moment that I think is still a little unclear. The World Intellectual Property Organisation is the normal international forum for discussions on this subject, but I think that the World Trade Organisation will be called upon to settle some of the disputes in this area because it is different in the sense that it has some teeth. If a country is not living up to its obligations it is possible that other countries could complain to the World Trade Organisation and, if that complaint is upheld, for retaliatory action to be taken. There is no mechanism of that sort in the World Intellectual Property Organisation sphere, so to that extent I think that there could well be a shift of emphasis towards the World Trade Organisation.

Chairman: Thank you very much, Mr Hartnack, Mr Wood and Mr Hoptroff, for coming today and for robustly defending the position of the Patent Office under existing legislation. Thank you very much indeed.

Letter to the Clerk of the Committee from TW Roberts, Chairman Biotechnology Committee, Chartered Institute of Patent Agents (9 December 1994)

I write in reference to Press Notice no 14, of 3 November (in particular paragraph 4.3), and to our telephone conversation this morning.

The Chartered Institute of Patent Agents (CIPA), founded in 1882, was granted a Royal Charter in 1891. A prime object was "to form a representative body of the patent attorneys in the UK for the purpose of promoting improvements in the Patent Laws and in the Regulations under which they are administered".

The Institute represents all UK patent attorneys and its activities cover all fields of intellectual property. CIPA draws its membership both from private practice and from industry, and is thus able to reflect the views of all holders of intellectual property rights, both large and small. The Institute has a number of specialist Committees, among them the Biotechnology Committee, at whose suggestion I write to you.

As lawyers with experience in this area, we believe that the patenting of DNA derived from human beings is appropriate under the same conditions as for other inventions. We recognise that there is public concern about this topic, but we think that much of it springs from misunderstanding. We believe that patenting is desirable to encourage research in this area, and essential to underpin commercial development. It allows the pharmaceutical industry to contribute to the advance of health care in the UK. If the industry does this well, it will also provide exports to help the country pay its way, employment for skilled staff, taxes to fund essential services and profits to pay shareholders and pensioners.

The main conditions for an invention to be patented are that what is claimed is:

new;

not obvious; and

industrially applicable.

We do not support the patenting of discoveries, but only of industrially applicable products or processes. Nevertheless, it often happens that a new discovery leads to a patentable product or process. The latter must not be denied protection because it is based on an unprotectable discovery. Isolated DNA is a product: it can often fulfil normal patentability criteria, and we strongly oppose a ban on patenting it solely because of human origin. Equally, we do not support patenting of all novel DNA sequences. For example, where a known enzyme is well characterised and its function understood, there may be obvious uses for the DNA that codes for it, and it may be no more than obvious routine to isolate and characterise this DNA. Such DNA would not and should not be patentable, since no invention is involved.

Should the investigations of your committee turn up specific problems related to patents, we would welcome the opportunity to comment further. If there are real problems, we would like to help solve them, in accordance with the aims of our Charter. Proposals for legislation will need to take careful account of obligations under European law as well as other international arrangements.

Examination of Witnesses

MR T W ROBERTS, Chairman, Biotechnology Committee, the Chartered Institute of Patent Agents, and MR IAN ARMITAGE, Mewburn Ellis, examined.

Chairman

381. Mr Roberts, Mr Armitage, thank you very much for coming to give oral evidence to us this afternoon. You have the advantage, I suspect, of having been able to listen in and see how the discussion and questioning has been going. In relation to patent operations you are involved in the law. Mr Roberts, you I think are chairman of the biotechnology committee of the Chartered Institute of Patent Agents, is that right?

(*Mr Roberts*) Yes, Mr Chairman, that is correct.

382. And you, Mr Armitage, are a member of the firm of Mewburn Ellis and are a patent attorney, is that right?

(*Mr Armitage*) That is right, Mr Chairman.

Chairman: So we may proceed on that basis, may we, to offer you questions.

Dr Bray: Just for the record, Mr Chairman, I understand that Mr Roberts is employed by Zeneca.

Chairman: Right, thank you.

Sir Trevor Skeet

383. Would you indicate very clearly what you consider to be patentable—you are appearing at the Patent Office regularly—and what you consider to be non-patentable?

(*Mr Roberts*) I am sorry, Sir?

384. You are the legal man involved in this and you are appearing before the Patent Office regularly and you submit your specifications. You want to get your patent for your client. What do you consider to be patentable in the field in which we are involved and what do you consider to be non-patentable?

(*Mr Roberts*) Broadly, Mr Chairman, if I may start from the principles laid down, what is patentable is what is novel, what is not obvious and what is industrially applicable and the law also tells us that a discovery is unpatentable; only an invention is patentable. Now we have had some discussion this afternoon about the distinction between an invention and a discovery and I would suggest that this is really quite clear. A discovery is new knowledge; an invention is a new process or thing and if you start from that principle and you apply it to the subject matter that we are dealing with I think that you may find that it helps. This immediately raises the question as to whether you can patent a gene and there is a sense in my view in which a gene is quite unpatentable because the sequence of the gene is simply knowledge, but if you isolate a gene from an actual product you have material in a test tube which is quite new, which is industrially applicable and can be commercially most important, and it is very desirable that that material should be patentable, and I believe that it is, under the normal laws as they apply in other areas.

385. I understand that in the United States they have one idea that more and more should be patentable and the United Kingdom less and less in order to allow the knowledge to be used and for research to be fostered. What do you say on that issue?

(*Mr Roberts*) I think that there are differences between the United States and the United Kingdom

[Sir Trevor Skeet *Cont*]
in this area. I believe that the general view that we take in the United Kingdom is that patent rights apply primarily to commercial exploitation, and we have a research exemption for experimentation with the subject matter of an invention, to improve it, for example. That is very much less clear in the United States. There is also the difference in the United States that they have almost no derogations from what you can have in the subject matter area. For example, the only thing that is said to be unpatentable in US patent law is a human being.

Chairman

386. So that their law really does not exist in terms of the definition on which we operate here?

(*Mr Roberts*) There are not so many differences as that, Mr Chairman. I would say that there is more a difference of emphasis than of fundamentals. Occasionally it is said that European law is fundamentally different from US law because in the US you can patent a discovery and in Europe you cannot. But the fact of the matter is that the practice is very similar in both countries as to the patenting of discoveries.

Sir Trevor Skeet

387. Would you welcome a European directive on this particular subject along the lines that has now been agreed in a text between the Council and the European parliament?

(*Mr Roberts*) This has been a matter of hot debate I think within the profession and within industry. My belief is that the compromise that the Conciliation Committee has produced, although it is rather unclear in some aspects, broadly confirms the existing practice of the European Patent Office and will be accepted by industry and will be a welcome resolution of the discussion that has taken place over so many years.

Dr Williams

388. You mentioned the difference between American and British law here on patenting. Are there any difficulties that are caused by that?

(*Mr Armitage*) Some difficulties have been referred to which are not peculiar to this area of technology, that is to say, the first to invent versus the first to file, and other types of discrimination within the US patent system which discriminates to the disadvantage of foreigners. I do not think that we need to go into those particularly because as I say they are not peculiar to this area of technology. As Tim Roberts says, Mr Chairman, I do not believe that the apparent differences in the language in the law reflect as large a different in practice. There is one area of practice in the United States which is significantly different from ours, and that touches on this question of utility that Dr Bray was talking about earlier. The United States Patent Office does have quite a strong sense and element of law which requires utility to be demonstrated for an invention, particularly where you are claiming that you are producing a new substance and what is its utility. We do not have that so much here. There is no specific requirement for utility. Our requirement for industrial applicability is not at all the same thing, not nearly as strict. That I think is a difference which if we were to introduce a more stringent requirement for utility might go some way towards solving the problems but I have to say that in the United States you can still see very broad patents being granted.

389. Perhaps I can ask just one further question on this, Mr Chairman. We are in a rapid growing field, I think, and we are still in the early days of its development. Would it present any difficulties if there was an international consensus to say that DNA sequences are not patentable?

(*Mr Roberts*) I believe that it could present considerable difficulties. It would depend on the detailed wording of it. All these—and I have to use words like arbitrary and artificial, which may appear to be derogatory, but that is not really intended, Mr Chairman—extra restrictions on the type of subject matter that can be patented over things that are new, not obvious and industrially applicable always cause difficulties in arguing about the borderline and they introduce areas and considerations which become more and more arbitrary. If you say that we cannot patent—

390. If I can just intervene here, I think that there is a consensus in this Committee and among scientists that DNA sequences are pure knowledge and it may have taken a lot of invention to get to that pure knowledge but there is a kind of consensus emerging that those should not be patentable. Now that is simple and clear. You do not need pages of memorandum to explain it, and if we just have that as a one sentence consensus internationally what difficulties would it cause?

(*Mr Roberts*) You are talking about natural DNA sequences rather than DNA sequences which are created in the laboratory?

391. I am talking about the genetic material, it is the natural DNA sequence.

(*Mr Roberts*) No, I am sorry, it is quite often not the case that all that you have done in the laboratory is to clone it and multiply it. You may well put different bits together and produce novel vectors where you get one bit of DNA from one place and another bit of DNA from another place and you produce something which has completely new properties. Now I would certainly hope that you would not go down this road of providing even the natural DNA sequences are unpatentable. There is also the question of whether they are really patentable at the moment. A claim to a natural DNA sequence is in my view either a discovery or anticipated by what already exists in nature so there normally has to be some distinction between the thing existing in nature and what you have claimed.

Dr Lynne Jones

392. What sort of completely new properties can the DNA have in a test tube and not in vivo?

(*Mr Roberts*) The natural DNA?

393. Yes, you are saying you are taking bits of DNA but in vivo the different bits of DNA work together although there may be different nucleotides bases separating them?

[**Dr Lynne Jones** *Cont*]

(*Mr Roberts*) Yes, you take one bit of DNA from one place and another bit of DNA from another place and you produce a new sequence which has never occurred in nature.

394. I know, but you said properties?

(*Mr Roberts*) Well, it will not have any new properties until you introduce it into an organism where it will be effective, and there it will have some properties.

395. It produces the same protein?

(*Mr Roberts*) It may inhibit the protein.

Chairman

396. It may have a different purpose?

(*Mr Roberts*) These are all sorts of technical developments which can be extremely surprising—they do not always work as you expect. I would be very distressed by any sort of general line which says: we regard this as obvious per se regardless of the actual fact.

Mr Batiste

397. I suspect that there are differences between us such that we are not quite following the stages of your thinking. Perhaps you could help us if we just go through it again stage by stage. You heard from the Patent Office that a gene of unknown utility would be unlikely to be patentable now and presumably that you would accept. Equally we have heard that you can take genes and take substances from them—we have seen some applications in our visits already on that—and I do not think that there is any difficulty at that end that that clearly should be patented. I think that what causes the difficulty is that we want scientists to be able to continue with the genome mapping programme and we have heard very clearly that many hereditary diseases are the consequence of four or five or six genes interacting in different ways and the concern that I think most of us have is that if someone discovers what a particular gene does—simply, not the question of extracting it from its natural state and making a useful product from it—if someone merely discovers what one particular gene does it is going to complicate and slow down and perhaps make too expensive the research process of trying to work out what the interaction of the genes may be within a human body, and that is where I think that we have our difficulty. Now can you help us with that?

(*Mr Roberts*) Am I understanding you to say that your concern is that if these genes are patented the research will have to stop?

398. Certainly the evidence that we have had is that basically it would be very much inhibited. If you can satisfy us that it would not be inhibited, then obviously that attitude is quite different?

(*Mr Roberts*) I find it difficult to see how the research would be compelled to stop. It is the commercial application that the patent is going to be granted to.

Dr Lynne Jones

399. I have a letter here from The Times written by Professor Roger Williams which says that one research project has been dropped because Chiron has got its own patent.

(*Mr Roberts*) One would have to know the background for that as to whether it was that the funding had been withdrawn by a commercial company because they did not think that they were going to get a licence from Chiron or whether there was concern from the Medical Research Council that they would be encouraging the infringement of a patent. If it is the latter I would be very surprised.

Chairman

400. Would you like to come in here, Mr Armitage?

(*Mr Armitage*) Mr Chairman, yes, because I have had some personal experience although acting for large companies as I also act for smaller research enterprises, and I am also involved in the hepatitis C. The problem as I see it is that there is a certain amount of funding—public funding, MRC funding, whatever you call it, and there is also other funding from industry some of which comes in at the early stages in funding the research project. Other of it comes at the later stage when some research has been done and you then want to carry on towards the market place. Whichever it is, if it is commercially derived funding, then the commercial entity is going to want to see some return as a general rule. If they see that the possible commercial exploitation of what they are being asked to fund is going to be blocked by a patent such as the hepatitis C Chiron patent, then they may well withdraw or not provide that funding for the initial research or for taking research on to the market place subsequently, and I entirely agree with that aspect. I did not see the letter, but I entirely agree with that aspect.

Mr Batiste

401. Would it then be logical from what you have just said that the blocking of the line relates to the commercial exploitation that follows, so why then should there be a patent merely on the basis of what a particular gene sequence does? How can the mere description of the function of a gen itself be patentable because that is not related to a commercial exploitation until you do something further? Clearly when you do something further, if you take out a body and develop it and inject it into an animal to produce a hormone to produce a protein, that could all be patentable, but why is the mere discovery of the function of the gene?

(*Mr Roberts*) I would say that it provides a new process, of industrial application. To the extent that it does that it is patentable. To the extent that it does not do that, it is not patentable.

Chairman

402. But the discovery of what a gene does in that way comes a bit closer to intellectual property than it does to a patent, does it not? It is a piece of knowledge?

(*Mr Roberts*) It is a piece of knowledge, but most patents in the chemical area are based on new bits of knowledge. You use the new bit of knowledge to produce a new product or process.

Dr Bray

403. But is there not some danger that patenting will inhibit basic research? If you look forward to the continuing interaction between basic research and industry, for example on how genes are switched on and off, on how this controls how the embryo develops, then matters will continue to be hugely important in pharmaceutical terms and in research. For the health of both it is most important that there be an easy communication between the two. Are you worried about too rigid definitions of what is patentable inhibiting the freedom of research and damaging the interests of the pharmaceutical industry itself?

(*Mr Roberts*) I am concerned that we maintain a balance between the inventor and the public. In the patenting of genes our view would be that that is reasonably maintained provided that you do not get patents granted of too broad a scope which are too speculative or which have no utility whatever of a practical nature. As to how patents would be relevant to development, that important new knowledge would undoubtedly give rise to some patentable inventions, and they might be of a slightly different type from this gene sequence type that we have been discussing.

Mrs Campbell

404. Mr Chairman, the question that I was going to ask has already been answered so perhaps I may move on and ask something else. Listening to what you say it seems to me that a rather subjective judgment comes in at some stage about how close to the market place a produce has to be before it is patentable. I think that what we are worried about is that if it is very far away from the market place it could curtail all other development, and a very wide range of development, and that is the danger. But I wonder whether you feel that the situation has changed in view of the events of the past few months and whether there has been any change in that very fine judgment about how close to the market place you have to be?

(*Mr Roberts*) I would say not. Generally when these new inventions get to the Court of Appeal, the Court of Appeal looks at them with a fairly sceptical eye and it is doing the work, I would say, to preserve the balance between the patentee and the public.

405. What about the patenting and the academic research? We have heard from a number of people who have said—for instance, Dr Martin Bobrow—that people say you will not get proper commercial exploitation of this information unless the people who wish to exploit it have a patent, but the converse is that if one group have a patent you are absolutely sure that no one else will ever touch that so if they choose not to develop it, and they may well not for a variety of reasons, you can box yourself into a corner of absolute non-exploitability. Would you say that that was a danger?

(*Mr Roberts*) I think that it can be a danger. There is also the opposite danger though that if there is no patent protection available for a particular development commercial companies are not going to spend money on developing, on safety research and on various things of that nature to bring the thing to the market. I still do not really understand why the research cannot continue. If people are doing research and they find some useful improvement (a) they may be able to patent it themselves (b) they will have a case for going to the owner of the patent and saying, look, this contributes to the initial invention that you have already made.

Chairman

406. Could we just ask on that point and take your own company. Patents have been taken out on this or that gene. Does that in any way affect the direction of the research that your own company wants to go in? Do they look at the patent issue each week? Do you advise them "You can't do that because ... "? Is there a discernable effect as between the degree of new protection being taken out and the direction of Zeneca's research?

(*Mr Roberts*) Certainly Zeneca studies the patents very carefully as they come out week by week and when planning an area of research you look to see what is free before you start your research work, but because somebody else comes out with a patent on the area that you are working on you do not necessarily give up. This happened to Zeneca specifically with the tomatoes that we are hoping to bring to the market. Somebody else came out with a very relevant patent application slightly earlier than ours, but we continued with our research and we negotiated with them and we achieved a settlement which enables us both to sell in different market areas, and I would regard that as the sort of thing which should happen in this area.

407. Mr Armitage, do you have any comments to make in this respect?

(*Mr Armitage*) I do not feel very competent to comment on research companies' judgments as to what they do, Mr Chairman.

Chairman: Very well, thank you.

Mr Powell

408. I wondered whether you had got any opinions which you would care to offer us as to whether patent offices are too lax in applying the criteria of novelty and inventiveness to biotechnological patents? You mentioned, I think, Mr Armitage, that the United States was granting some very broad patents indeed and I am wondering whether you have got any opinions for us about different standards that may applied here in different countries?

(*Mr Roberts*) There are sometimes problems in the biotechnology area. It being a new area, the Patent Office has to develop its practice. It is not like

[**Mr Powell** *Cont*]
chemistry, which is an area that I am more generally familiar with, where a practice of the right sort of claim has built up over many years. There is a tendency, not only in the United States but we also get it in the European Patent Office, that occasionally very broad patent claims are granted on what appears to be an inadequate basis. Somebody does something for the first time and they get a claim to all ways of doing that, and that to my mind is very much a type of claim that does not preserve a proper balance between the innovator and the general public, and there is a difficulty here in that due to a technicality of European law the question of the scope of a claim, quite apart from questions of novelty and obviousness, cannot be raised after grant. It is purely a matter for the patent examiner. So, if the patent examiner gets it wrong, then there is no way of challenging that.

Dr Williams

409. I wonder if I could just flesh out your background in Zeneca and your role as chairman of the committee on biotechnology, in terms of which you are presumably concerned with genetic engineering. What I am trying to say is that the principles which apply to genetic engineering of plants and even of animals are not entirely appropriate to human genetics. Would you accept that, and am I right about your background? Would you accept that it could be the case that while there are laws that apply to the tomatoes, for instance, when it comes to human genetics we need much higher standards or a different type?

(*Mr Roberts*) You are absolutely right about my background in Zeneca: it is in plant science. My background as chairman of the CIPA committee on biotechnology is much more general than that, but I would not be ready to accept that different principles should be applied in the two areas. You do not want to make up the law specially for each new technical area that comes along. You want to take as far as possible the principles of patent law over the whole area of technology and apply them consistently.

410. But laws in human genetics may be different from those in agriculture?

(*Mr Roberts*) Legal regulatory mechanisms?

411. Yes?

(*Mr Roberts*) Absolutely, yes.

Dr Lynne Jones

412. What do you think of the strategy of companies like Human Genome Sciences who propose that they would make their patents available to researchers provided that they have the right to any commercial application or new discoveries?

(*Mr Roberts*) These are patents of the NIH type whereby you list 2,000 gene segments and you then—

413. But that presumably has been stopped anyway, has it?

(*Mr Roberts*) That particular application has been stopped, has been withdrawn, and we hope that patents like that are not going to be granted, but I have no doubt that there are a number of patents of that sort pending in America on behalf of commercial companies.

414. And what do you think of that? In this country that would not be permitted if there was not a known use of the commercial application already, but it could happen in America, is that correct?

(*Mr Roberts*) We do not know, we will have to see what the Patent Office says. What happened to the corresponding NIH application in Europe when it was examined under the PCT was that they said, all these 2,000 gene sequences are separate inventions and if you want this invention examined you must file another 2,000 applications at 10,000 marks a time, or whatever it was. Had that not been withdrawn, that would have put a stop on that, but I do not know that that answers your question. Basically, however, I do not think very much of them.

415. It is still theoretically possible for a company to amalgamate a number of known gene sequences with perhaps very little application, but potential application, and get patents, and then offer them to research. In effect, will that not inhibit research by other companies, that kind of approach?

(*Mr Roberts*) I believe that that is contrary to the existing law and if patents like that get granted—and patents do get granted that ought not to get granted from time to time, and this is an inevitable facet of the system, that examination cannot be perfect—I believe that when patents like that do get granted, nobody should take any notice of them[1].

Chairman

416. Mr Armitage, would you like to comment on that?

(*Mr Armitage*) I am not sure that Lynne Jones was really thinking of patents rather than the database which they have because most of their information is contained on database, it is not patented, and they were certainly offering either themselves or via Smith Kline access to their database under conditions which others, like the Medical Research Council, found unacceptable. That seems to me to be entirely between them and the people who want the information because they are not monopolising the information. Anybody else is free to set up their own database and do their own research and all they are offering is what is confidential information.

Dr Lynne Jones

417. But normal scientific progress relies on collaboration so basically they are hogging that intellectual property right rather than publishing it. Do you not think that that will actually inhibit research in this area?

(*Mr Armitage*) No, because what they have developed is that which they have or someone has paid for them to do. They are not preventing anyone else from doing it, which a patent, of course, does. It is a very important distinction.

[1]Footnote by witness: Of course, it would be most unwise of anyone to ignore a granted patent without taking specific and competent legal advice.

Dr Williams

418. I have just one quick question, Mr Chairman. What would be the consequences, Mr Armitage, if there was a ban on patenting naturally occurring gene sequences, allowing perhaps artificial or synthetic variations on it? What would be the consequence of doing that?

(*Mr Armitage*) From one point of view it would be almost nil because I cannot at the moment think of a patent that had a claim directed to an intact human gene. It is nearly always directed to a small, often very small albeit very important, component of a human gene. If you are saying that any part, any DNA fragment, from a human gene should also be unpatentable, then you run into all kinds of difficulties as to how small does it have to be, and when you get down below about 20 bases you are entering the area where it is going to occur statistically in the human genome anyway and what happens if you have got a patent for a gene fragment or a DNA fragment which you think is not naturally occurring and it turns out later to be naturally occurring—is your patent then invalid? You can see that by making ad hoc legislation of this kind you increase the boundary of uncertainty, you create work for lawyers like myself, which I am very happy with, and you—

419. No, quite the converse was the intention, I promise you!

(*Mr Armitage*) Of course, I appreciate that!

420. I should have thought that if the law was quite clear and everything was there before that did not take our inventiveness to find out, when it is just pure knowledge, if all that is done is to uncover that truth that is always there, why should there be that difficulty, whether it is 5 bases, 20 bases or 3,000?

(*Mr Armitage*) You are dealing with two different issues here. One is whether it should be patentable in principle and the other is whether as a matter of social policy one should create a special exception to existing normal rules of patentability. Now I would address the second one because I think that the first question is already well established. You can patent a known substance from nature that you have newly discovered and characterised. That is so well established that you are not going to put that genie back in the bottle. The question is in relation to the human gene as DNA, as chemical substance, should we or should you or should the government create a special exception to patentability for that, and I would say that in general ad hoc legislation should be restricted to those circumstances where it is absolutely vital that it be created such as, for example, was done in the case of copyright for computer programmes. It should be addressing a particular and very serious concern and need, and I do not believe that in this case there is or has been demonstrated such a need to create ad hoc legislation.

Chairman

421. Right, thank you for that, Mr Armitage. Let me conclude on a rather banal question. You heard us talking about the European Patent Office earlier with our colleagues from the British Patent Office, so we should like to ask your opinion—users of the system—and whether you would care to comment on the experience that you have had with the European Patent Office, has it done its work effectively and, in so far obviously as patents can be challenged in the courts, what is the sort of cost that is involved in making such a challenge?

(*Mr Roberts*) The general operation of the European Patent Office I would say from the point of view of industry and the professionals dealing with it has been extremely satisfactory. I think that since its birth the European Patent Office has been aware that it has competition from local offices and it has to provide a service that will be of benefit to applicants. I would perhaps say here, Mr Chairman, that I am a little concerned about the possibility of the ratification of the CPC—the Community Patent Convention—which will change from a bundle of European patents being granted by the European Patent Office to a unitary Community patent because it appears that if we have such a patent it is going to have to be translated into all the languages of the European Community and because of the expense nobody will use it—there will be about three patents a year!

Sir Trevor Skeet

422. May I just follow that one up, Mr Chairman. In view of your experience as practitioners would you like to see any modification of the 1977 Patents Act or the 1988 Act?

(*Mr Roberts*) Personally I would refer specifically to a point that that came up earlier, that is, the point that it is not possible to raise the question of fair basis for a claim after the examination process so that a third party cannot come along and say, all right, your invention is new, but it is being claimed far too broadly. That is a small change that a number of people would like to see made.

Chairman

423. Mr Armitage, would you like to add to that?

(*Mr Armitage*) Yes, Mr Chairman, thank you. The comptroller-general obviously had forgotten that particular point when he said that all of his decisions were capable of being challenged in the courts. That particular one is specifically excluded. There is a strong body of opinion in this country that it should be altered. We had the same problem with the European patent convention. The European patent system, the European Patent Office fees, are much too expensive, they charge for the wrong things—that is to get the patent. On the question of challenging I can speak from the point of view that I send the bills out to clients. Bearing in mind the extent of the European patent it is not particularly expensive to challenge it as compared, for example, to the United States. To challenge a United States patent, if you can do it at all, is hideously expensive. The European system works rather well. It is over-priced in certain key areas. The national patent offices of national governments are taking a huge rake-off for doing nothing, including our own. We do need this ability to challenge after grant the breadth of the patent claimed. If there is anything else, Mr

[**Chairman** *Cont*]
Chairman, I would say, improve or tighten up or have a more strict requirement for the utility of the invention, and this might address the question of sequences of no known utility, and I would put in a plea for the ability to use compulsory licence provisions in the British Act and elsewhere, a harmonisation of the compulsory licence provisions, which has been flagged up in TRIPS but I do not think that it is very user friendly, and this would also address some of the problems about whether you free to use the downstream research which someone has already developed.

Chairman: Very good, thank you for that, Mr Armitage.

Dr Lynne Jones

424. Can I just ask on this convention, on the breadth of patent. I have a report here from Nature about the House of Lords case in Biogen, and they have overturned their patent based on the fact that the claims made in the patent were too broad, so is that going to set a new precedent?

(*Mr Armitage*) You can indirectly attack the breadth of a patent claim on the basis, for example, typically that it goes so wide that it is claiming that which is obvious and therefore it lacks inventiveness, or that it includes things for which the patent description does not provide an enabling disclosure. Now it is often said by the European Patent Office that this is an adequate remedy. I do not believe that it is, and it is not felt to be.

Chairman: Thank you both very much for coming and giving us your views on these matters. We are very grateful to you, Mr Roberts and Mr Armitage.

Memorandum from Mr Ian Armitage following oral evidence given on 8 February

1. *What would count as a discovery, and so be unpatentable, and what as an invention?*

There is no doubt that the elucidation of the sequence (formula) of a naturally occuring gene or other DNA constitutes a "discovery", and "as such" is specifically excluded from patentability in Europe at least.

However, many patentable inventions are based on discoveries, and it is an integral aspect of the patent system, which is certainly not going to change in the foreseeable future. Such inventions arise in virtually all fields of technology, and biotechnology is not peculiar in that respect.

The question, therefore, is the meaning of "as such"; and related to this, the nature and extent of the patent protection that *is* allowed based on such a discovery.

One must distinguish between the DNA *sequence* and the DNA *itself.*

The "sequence" is the chemical formula of the DNA, and is therefore mere "information". One cannot therefore patent "the sequence". As the opponents of patentability in this area would say: "the sequence is God-given" (or words to that effect).

The DNA however is a chemical substance, of precisely known (or knowable) structure and formula. It can be manufactured on an industrial scale, whether by extraction from a natural source or by chemical or biochemical synthesis; it can be bought and sold, and held in the palm of your hand. It is therefore *not* information "as such".

It is now firmly established in patent law and practice in virtually all countries that one can patent a chemical substance per se, so long as it has the necessary qualities of "novelty" and "inventiveness", and that its production can be carried out on the basis of the patent disclosure.

One may debate whether there can be "novelty" in a chemical substance which already exists in nature, and whether there can be "inventiveness" in isolating and characterising the substance and describing how it can be made or obtained. Suffice it to say for the present purposes that under the principles of patent law and practice, the answer is "yes" to both questions. This is a genie that will not go back in the bottle.

Therefore, provided that the specific circumstances of the individual case indicate that the requirements of novelty, inventiveness and sufficiency of patent disclosure are met, the *DNA* (the chemical substance per se) which represents a gene or a part of a gene is patentable, and will continue to be so, unless specific law is made to exclude it from patentability.

The making of such ad hoc law should, in my view, only be undertaken when there is an overwhelming requirement for it. In general, ad hoc law tends to create more problems than it solves. I comment on this below.

2. *Would other IP protection mechanisms, eg, copyright, be appropriate for protecting DNA sequences (not developments based on them)?*

No.

Copyright is in principle intended to protect an author's artistic creations. One can ignore the "artistic" bit, which is very loosely interpreted; but so far as *natural* DNA sequences are concerned, of course, these have not been "created" by the hand or mind of man, and so should not be regarded as the copyright of anyone.

So far as artificially devised DNA sequences are concerned, these *have* been devised by the hand or mind of man, and can therefore constitute a patentable invention in the normal, and largely uncontroversial, manner.

The contentious issue largely concerns *natural* DNA sequences; and copyright simply isn't a suitable form of IP protection for the sequences (ie, the sequence "information") per se.

There is however a possible area in which copyright *might* be applied; and that is in relation to the protection of the DNA sequence information which is stored on the databases (or in the lab notebooks etc) of the scientists who discover them. That would be to prevent others from *copying* the sequence information derived *from that source.* It would not prevent others from elucidating the sequence information independently.

This kind of copyright protection, if it existed under the present copyright law or some special addition to that law (as was done for computer programmes), would however be primarily for the benefit of those who have such databases, and would create *additional* restrictions on the use of such research results, thereby only aggravating the concerns of those who want to see such results made more freely available.

In short, I think it is a non-starter.

3. *What might be the consequences of simply declaring naturally occurring sequences unpatentable?*

This would be a piece of ad hoc legislation of the type I referred to above. It would create a special exception to an established category of patentable subject matter (chemical substances per se).

As I suggested, there ought to be *overwhelming* need for such legislation before it is introduced; and I do not see such a need at present, partly because the problems with the persent situation (insofar as there are any) are not shown to be sufficiently serious, and are not necessarily addressed adequately by such a move.

Also, it would be a measure difficult to define and enforce. I indicated above that ad hoc legislation can introduce more problems than it solves. In particular, it creates a new and extended legal borderline, which then has to be interpreted by the courts in "borderline" cases, to the obvious benefit of lawyers, but few others.

> For example, would the exclusion apply to sub-fragments of naturally occurring sequences; and if so how small? As you get to DNA fragments which are below about 20 bases, you are entering the region where it becomes statistically likely that *any* DNA sequence you care to think of will in fact occur in nature.
>
> And does the exclusion apply if the natural DNA sequence is modified or has a different DNA sequence added to it? This is the *normal* situation in practice when one is utilising natural DNA sequence information.
>
> And would a patent on an apparently non-natural DNA sequence suddenly become invalid if it were discovered that the sequence does in fact occur in nature?

These are just some of the joys that await the introduction of such a measure, and one could foresee many others.

4. *What is or will be the effect of the patent system on research?*

One could perhaps look at the kind of patent claim which is produced at present, and which is presumably the target of such a proposal.

> The research team elucidates the DNA sequence of part of a natural gene; a result which is of some importance and potential benefit to mankind. (The "cystic fibrosis gene" is a case in point).
>
> Note that they would probably not elucidate, at that stage at least, the *entire* gene; and it is seldom that the entire gene would be required for any practical application of that discovery. Indeed, with human genes it is usually a *very* small (albeit very important) part of the natural gene that is required.
>
> Suppose the actual or potential practical applications include (as they did for CF) a diagnostic test, the therapeutic administration of the protein encoded by the "normal" gene (ie the gene not having the defect), and the therapeutic administration of a (usually non-natural) form of the normal gene suitable for generating the protein in situ in the patient.
>
> One of the monopoly claims which I would expect the inventors to include in the patent would be along the lines:
>
> > A DNA isolate encoding a protein having the amino acid sequence depicted [in the patent] and having the property.....[eg of doing that which the normal gene does in non-CF individuals].
>
> Another would be:
>
> > A DNA sequence containing the [eg CF] defect depicted [in the patent] and capable of distinguishing by hybridisation between a gene carrying that defect and a gene not carrying that defect.
>
> Yet another would be:
>
> > A protein having an amino acid sequence depicted [in the patent] and having the property . . . [eg of doing that which the normal protein does in non-CF individuals].

There would be other claims, eg to diagnostic kits and therapeutic formulations, but the above type of claims are probably the ones that would have the most restrictive effect on the activities of others who were seeking to build upon the original work.

Other scientists may legitimately want to build upon that work, and it is certainly in the public interest that they should be able to do so.

They may have been already involved in the same line of investigation when they were "beaten to it" by their rivals, or they may start on it after seeing the initial results.

The foregoing type of patent claims do not prevent such research, since non-commercial research based on the patented invention is not an infringement of the patent. The problem is that they may not be able to get commercial funding or to develop commercial enterprises for the exploitation of their further work, eg because it is unclear whether licences will be available under the original patent, or the terms of such a licence are too onerous.

5. *To what extent does the ability to patent genes distort companies' research priorities?*

[Not really for me to comment.]

6. *To what extent can patent offices detect claims that are too far removed from the patent to be easily achievable?*

It is well established that one patent monopoly can validly dominate later (patentable) inventions, eg for an unobvious improvement or development of the basic invention.

However, sometimes a patent monopoly can be unacceptably broad, in the sense that it *specifically* monopolises that which the original inventors have not invented.

In the case of the CF research, the original researchers who elucidated the CF gene would have foreseen the *possibility* that this could lead to some kind of therapy for CF, but it was most unlikely that they could at that time have predicted precisely what it would be, and have provided in their patent an enabling disclosure for such a therapy.

Therefore, one might say that if their patent included a claim specifically to the therapeutic use of the DNA or the protein encoded thereby, that would have been unreasonably broad, since it was an invention yet to be made.

Unfortunately (in my view, and the view of many others), there is a lacuna in the present European patent law which tends to exclude any effective challenge to the patent after grant on the ground of undue breadth of claim; so it depends very much on the patent office examiner getting it right before grant, and there have been some cases where people feel quite strongly that the examiner got it wrong.

However, even with an amendment to the patent law in Europe to remedy this, I am not sure that it will really address the underlying question (problem) here. In the notional scenario indicated above (with reference to a CF-type of case), the claims to the DNA and the encoded protein would probably not be affected by such an amendment to the patent law, since they are not directed *specifically* to an invention yet to be made (such as CF therapy), but to an invention that clearly *has* been made, and described in the patent.

What therefore could or should be done to alleviate the perceived problem of inhibition of "downstream" research? Indeed, is it a real and substantial problem at all?

There are many aspects on which scientists have expressed concern to my knowledge. Some of these are better founded than others; some are based on misunderstandings of patent law, and are alleviated to some extent when the law is explained to them. I will just consider the aspect indicated above, of dominating patents (eg including claims to natural DNA and protein encoded thereby) inhibiting the *commercial* funding and exploitation of research by others based on the original patented disclosure.

The main problem, as I see it, is uncertainty. Those funding the later research need to know that they can exploit the results and get a return on their investment. They need to know that they will not be held to ransom by the dominating patentee (ie the licence terms will be reasonable).

There are compulsory licence provisions in the patent laws of most countries, but primarily to prevent abuses of monopoly, and to protect the public interest (eg if the exploitation of an important invention is being prevented by the dominating patent). However, the compulsory licence provisions are seldom used, and therefore there is very little body of law on which to base good advice to the later researchers and their backers. Also, it takes years before you can even start a legal action to obtain a compulsory licence.

I do not need to go into detailed discussion of this question here. It would be a major subject in itself. Suffice it to say that, in my view, a modification of the compulsory licence laws, and their harmonisation throughout the patent laws of the major industrial countries, would be a much better way of addressing the most serious and legitimate concerns of science and industry, than any kind of ad hoc legislation to exclude certain specific types of subject matter from patentability.

Comments arising out of the Meeting of the Committee on 8 January 1995

A. Arising out of the questions to the Patent Office representatives

1. *(From Dr Lynne Jones) Is there a value in national patent offices alongside the EPO?*

Limited value in the biotechnology field, in my experience. Inventions in that area are generally expected to be exploited on a very wide scale, so that very few will be interested in obtaining patents in just UK or one or two individual countries. The emphasis is increasingly in centralisation of patent application and grant procedures; and in principle that is generally beneficial.

However, British patents are obtained more quickly than European patents, so some companies do sometimes file nationally in one or two important European countries **in addition** to the European Patent Office, so as to be able to pursue infringers at an earlier date.

The situation will be different in some other branches of technology, eg for the inventor of the improved mousetrap, but even then, the EU means that overwhelmingly commercial enterprises are thinking of exploitation, and hence patent protection, on at least that sort of scale.

The UK Patent Office used to have a useful function in providing a search or examination service or option under the operation of the European Patent Convention and Patent Co-operation Treaty, but those functions have been effectively removed or relinquished, to the regret of many in this country.

2. *(From Anne Campbell) Does the Patent Office have the qualifications and expertise to examine patent claims which are too broad?*

It has the legal obligation to do so, but it is questionable whether in practice it does so effectively. In this respect, it is probably not very different from the EPO. As the Comptroller said; examiners are human, and can get it wrong. The Comptroller was however in error in saying that *all* decisions of the Patent Office can be challenged in the courts. Specifically, undue breadth of patent claim is *not* per se a ground of invalidity after grant (the same goes for patents granted by the EPO). This is a matter of growing concern, in this country in particular, and there are moves afoot to try and have the patent law (here and at the EPO) amended to remove this oddity, and thereby open up to re-examination the decisions of the all-too-human examiners as regards the granting of patent claims which lack adequate support.

3. *(From Cheryl Gillan) Is it reasonable to grant patents for "the last piece in the jigsaw"?*

At first sight it seems unreasonable that the entire monopoly should go to the one who completes the job, building upon the probably much greater of work of those who went before.

However, if the earlier workers are unhappy about this, they should have kept their results to themselves until they had progressed the work to the point where a patent application could be filed.

I know that this looks as though it is inhibiting early disclosure of scientific results (it probably is), but this is how *commercial* enterprises conduct their business. If scientists choose not to operate in the commercial environment and manner, then it could be said that they have largely removed themselves from the debate as to how commercial enterprises should deal with each other (which is what patents are basically about). (That is of course an over-simplification, but it will do as a starting point for further discussion.)

4. *(From Cheryl Gillan) Are there any changes needed in the patent law?*

The Comptroller thought probably not. I think that there are some. I have mentioned the introduction of post-grant challenge to patents on the ground of lack of support and undue breadth of claim.

Also (following up a supplementary question from Sir Trevor Skeet), I think one *might* introduce a more stringent "utility" requirement (rather as they have in USA), not so much to deal with existing patents, but to deal with the case of patent claims directed to DNA (or other substances) for which there is no known or demonstrable practical usefulness. (I am not necessarily advocating this, as I am not sure how real the problem will turn out to be; but the existing requirement for "industrial applicability" in the present European patent laws will be completely ineffective for that purpose.)

I also think that the compulsory licence provisions of the patent law could be looked at as a means to try and provide a greater degree of certainty that useful "downstream" inventions will be permitted commercial exploitation on reasonable terms. This will however be hotly opposed by many established research-based companies; and it is likely to founder for political rather than objective considerations. It would also be no good if it were done unilaterally; it would need an international agreement, since the exploitation of this technology is international and not parochial. Article 31 of the TRIPS agreement deals with compulsory licences, but its provisions are pretty anodyne, and more likely to hinder than help in providing the kind of commercial certainties which I have indicated.

5. *(From Dr Lynne Jones) Why should genes be patentable, rather than the process by which the gene was discovered or the process by which it is subsequently used?*

The process by which the gene was discovered is generally irrelevant to any meaningful patent protection. It is of largely historical interest only; it is done only once; and it is not industrially exploitable in any obvious manner.

The process (usually more than one of them) by which the gene can be used certainly is patentable.

The question is why should the gene (or more properly the DNA which makes up the gene) *per se* be patentable? The answer is that patents are granted for *things* as well as for processes. DNA is a chemical substance, and chemical substances are a category of "things" which can be patented.

Even naturally occurring substances can be patented, if their existence was previously unknown or not accessible to the skilled person in an obvious or routine manner.

That is part of the patent practice in almost all countries, and it is not going to change in the foreseeable future. It works well enough in most cases. If it is thought not to work well enough in the case of gene-derived DNA, then it is for those who think that to show clearly, and not be mere slogans and other waffle (I am *not* referring here to the members of the Committee), precisely what is the overwhelming harm that is being done, that would justify and be remedied by making an ad hoc exception to the general rule of patentability in the case of gene-derived DNA, whether human or otherwise.

6. *(From Dr Lynne Jones) It is reasonable that other later workers should be obliged to pay royalties for their inventions relating to the use of a patented gene, even though it owes nothing to the earlier patent disclosure?*

The general assumption is that the initial "discovery" of the gene (the cloning and isolation of its DNA and the elucidation of its sequence) is seminal to the later work; that the later workers could not obviously have made their developments without that information. On that basis, therefore, the later invention *would* owe an essential element to the original patented invention.

The problem in practice is usually, not that royalty payments are demanded, but whether the patentee is willing to grant a licence at all. *Then* one can worry about the size of the royalty and other conditions demanded by the patentee. However, the latter worry is largely a commercial concern; and pure research is probably only inhibited to the extent that a commercial source of research funding may be denied if the sponsor considers it unlikely that a licence under reasonable terms will be obtainable from the earlier patentee.

7. *(From Dr Alan Williams) Is the assessment of inventive activity much less than it used to be? (presumably implying a fall in the standard of patent office examination of patent applications)*

I do not think so. Certainly, with the 1977 Patents Act the UK Patent Office has, *for the first time,* been empowered to assess patent applications for "inventive step" during the examination procedure.

There is a problem in biotechnology that the protocols for doing the research often look simple, but their execution can be horribly difficult. Questions such as these were addressed by the Court of Appeal in this country in connection with the case of Genentech vs Wellcome in 1987, and they held that Genetech's work in that case was not inventive. I think that the Court took too abstract a view of the matter; failing to relate the granting and maintaining of patents to their commercial function in protecting and rewarding investment in research and innovation. However, I would hardly have expected the British courts to consider such matters; it goes totally against the British legal tradition. In contrast, the European Patent Office, perhaps encouraged by the express concerns of the EU Commission that the patent system should have this function and not disadvantage European industry in relation to eg USA, has taken a much more pragmatic line in assessing inventive step in this new and difficult terrain.

8. *(From Anne Campbell) Does the patenting of gene sequences inhibit the funding of scientific research into developments based on something that has been patented?*

There is some evidence that it does (from my own experience). "Blue skies" research funding of course has no strings (or shouldn't have), but the prospect of not being able to exploit commercially research results because of an existing patent can inhibit *commercial* funding of a research project, or the chances of the research results being taken up by a commercial partner, or the setting up of a new enterprise to exploit the research results.

I believe that there are instances in all those categories, but I also suspect that they form a very small part of the whole spectrum of commercial activity. Nevertheless, I do feel quite strongly that one should nurture these small seedling projects, as they are a source of many exciting enterprises (who often go on to adopt just the sort of defensive and exclusive patent policies themselves in turn!).

9. *(Comment from the Comptroller-General) During examination of patent applications we err on the side of granting the patent because* all *our decisions are challengeable in the courts*

It is probably true that the UK Patent Office gives the benefit of the doubt to the patent applicant. This is probably true to a lesser extent also of the European Patent Office, although I doubt whether the officials of the EPO would so readily admit it.

The Comptroller was wrong in one important respect, however, in that one *cannot* formally challenge after grant the decision of the patent office, whether the UK office or the EPO, on the ground that the breadth of the claims is not supported by the description. I have already commented on this; and it is obviously relevant to some of the Committee's considerations.

10. *(From Dr Jeremy Bray) A scientist cannot afford to challenge a patent*

This follows on from the Comptroller's comment above. The Comptroller said that a scientist would be funded by eg MRC, who would be able to mount the challenge. However, I think that this is misconceived. Apart from the fact that most scientists are employed in industry; even if one takes those who are not, most are funded by grants or by their universities, and neither of these sources provide the funds for challenging patents; nor should they have to do so (which is why non-commercial research does not constitute infringement of a patent). MRC is one such funding body, and I am not aware of their ever having challenged a patent in the courts, and I would be surprised if they were to do so.

It is of course true that an individual scientist could not afford the thousands of pounds that it would cost to mount an effective challenge to a patent. I do not think that it could be made much cheaper, since it is necessarily a difficult, complex an time-consuming process; nor indeed do I think it would make much difference even if it were much cheaper. Dr Bray's point surely is that people should not have to challenge patents if the Patent Offices got it right during examination (and, by implication, did not so readily err on the side of the patent).

This is at first sight an attractive argument; but from my experience I doubt whether it does in fact have much force. It gives the impression that there are hosts of invalid patents out there waiting to be challenged; that they are causing great inconvenience, which is not being alleviated because people cannot afford to challenge them. This is assuredly not the case. Most patents are probably immune to effective challenge; and most patents that cause serious inconvenience are challenged by industrial entities who can afford it.

As I pointed out above, research scientists, and non-profit research organisations, generally do not even have to consider challenging patents, since non-commercial research on the patented invention does not constitute an infringement. It is when one wants to exploit commercially the results of that "downstream" research that the question of infringement of other peoples' patents becomes important. From one point of view, it could be said that this then becomes a matter for the commercial partner (eg the pharmaceutical company) with whom the scientists collaborate to achieve the commercial exploitation. However, the assessment of commercial viability of exploitation of the research results, and in some cases the setting up of a new company to exploit the results, can be adversely affected by the risk of patent infringement. The problem may sometimes be acute at the individual level, but is small in relation to the whole picture.

This may be changing, however, if broad patents are granted for the determination of gene sequences; so that in the foreseeable future, it would become very common to have to try and obtain, and of course pay for, a licence under someone else's patent in order to utilise commercially a (human) gene.

Dr Bray commented that it did not seem to be a requirement that such a patent had to describe the practical utility of the gene. I think that there is some force in this. In USA there is a more stringent requirement that the patent show the "utility" of the invention; and that may suffice to inhibit the patenting of these genes. We do not have such a strict requirement in the European patent laws, and DNA, being a chemical substance capable of manufacture, is regarded as "industrially applicable" irrespective of whether it has any known practical use.

While one might wish for a change in the European law in this respect. I think that the existing law could be more effectively used by the Patent Offices; notably by applying appropriately the requirements of inventive step, claim support and sufficiency of disclosure. The patent offices would doubtless say that they are already applying those principles "appropriately", and from the perspective of the patent lawyer this is probably true. However, from the wider perspective of the patent system serving the community, and providing a balance between the public and commercial interests, the patent offices cannot be relied on to establish the ground rules themselves. In my view, they need guidance from those whose job it is to take this broader view. The proposed Directive could have been such an instrument, but unfortunately it seems to have tried to do too much in one go, and has got bogged down as a result. Better, in my view, to have gone for a series of short Directives on individual points; or even some lesser form of pronouncement which would nonetheless be noted by the patent offices in Europe (especially the EPO).

11. *(From Sir Trevor Skeet) Should the UK Patent Office be concerned with ethical issues?*

No.

Others have written cogently to the same effect; see for example the Letter and Memorandum by Professor Gerald Dworkin to the House of Lords Select Committee on the European Communities, Patent Protection for Biotechnological Inventions, Session 1993–94, 4th Report, pages 65-69.

Basically, the patent office officials have neither the competence nor the experience to deal with such issues, which should be a matter of primary legislation directed to the actual thing which is seen to be offensive. It is difficult to see patenting itself as having any serious moral or ethical dimension, when one remembers that a patent is merely the legal right to stop others from utilising one's invention, or to obtain a royalty for its use. A patent does not confer a right on the patentee to use the invention himself (a fact which is often not appreciated). Likewise, one does not need a patent to perform a particular activity, so that abolishing patents for morally or ethically offensive activities will do nothing to curb them.

Thus, to take the example of the "Harvard oncomouse" patent; the upholding of that patent does not give the patentee, or anyone else, the right to produce and exploit such oncomice, merely the right to stop others from producing and exploiting them or to obtain a royalty for their so doing. If *primary* (ie general, non-patent) legislation were to make the production and use of oncomice illegal, or to regulate that activity, the use of the patented invention would be subject to that law. In other words, that primary legislation, directed specifically to the supposedly offensive activity (the production and exploitation of oncomice) would achieve the aims of those who find that activity morally or ethically repugnant; and that legislation would apply to everyone, whether or not they had a patent for that activity.

In my view, therefore, ethical and moral issues are essentially irrelevant to patenting, and even if there were stringent and enforceable "morality" provisions in the patent law, it would not address the fundamental issue, and in particular would not stop the activity itself (which can be carried on without a patent). To have even the present, essentially toothless "morality" provisions in the patent law merely wastes the time and energies of everyone concerned on the very rare occasions that they are ever invoked.

12. *(From William Powell) Can we read anything into the fact that Patent Office decisions are rarely overturned by the courts?*

The Comptroller commented that this was because UK Patent Office pays scrupulous attention to the decisions of the UK and foreign courts (and the EPO), and therefore, by implication, that our patent office examiners' decisions are generally in line with legal precedent.

In my view, the rarity with which patents are found invalid (whether patents from the UK Patent Office or the EPO) has more to do with the incidence of challenge than the correctness of the examination procedure. Less than 10 per cent of EPO patents are challenged after grant. Of those, only about a fifth are revoked; the remainder surviving intact or with some amendment. Of those patents that are not challenged, I suspect that in most cases it is because they are not sufficiently important to the activities of others, or because the patentee grants licences to others who want to use the invention.

The corresponding figures for patents issued by the UK Patent Office will differ in detail from those for European Patents, but the principle is much the same. The UK Patent Office examiners apply essentially the same rules of practice as the EPO examiners—differing only in certain limited respects or in minor detail—and, as the Comptroller said, taking account of prevailing practice as reflected in the decisions of the courts and the EPO Boards of Appeal.

13. *(From Dr Lynne Jones) Are there any limits on royalty rates which a patentee can charge?*

Mr Hoptroff from the Patent Office said that there were not, and that it is essentially a matter for negotiation between the parties; added to which there was a provision in the Patents Act for compulsory licensing of patents.

I imagine that behind Dr Jones's question was the notion that the public (eg the NHS) could be held to ransom by a patentee who has a dominant patent; for example the patentee for the cystic fibrosis test or the patentee for the hepatitis C test.

So far as the NHS, and other public bodies, are concerned there are also "Crown user" provisions in the Patents Act in addition to the general compulsory licence provisions. Crown user is essentially compulsory licensing of the patented invention by "a government department and any person authorised in writing by a government department, for the services of the Crown". If the relevant department cannot agree an appropriate royalty rate with the patentee, it can be settled by the courts. Therefore, to that extent, there is a means for limiting royalty rates on Crown use of a patent. (Something to be taken into account, perhaps, in the rush to privatise?)

The more general compulsory licence provisions (Section 48 of the Patents Act) are intended to prevent an abuse of monopoly by the patentee, and again have provision for the Patent Office to settle the terms of the licence, including of course the royalty rate. Applications for compulsory licences under these general provisions are very rare. This could be because the parties usually agree terms between themselves. There are however occasions where the patentee refuses to grant a licence to others, and this can seriously affect the development of new businesses. More importantly, the *uncertainty* as to whether a licence will be available

at an appropriate time in the future affects such businesses, and makes it difficult for patent attorneys to give them useful practical advice where such patents, or more usually pending patent applications, are discovered.

In my view there is scope for amendment to the compulsory licensing provisions, and this would be to the benefit of the new small businesses which are a feature of our economic recovery and future prospects. For example, at present an application for a compulsory licence cannot even be *filed* until three years after the date of *grant* of the patent in question. The date of grant is very uncertain, particularly for European Patents, and can be several years after the application is filed. I do not see any overwhelming reason why an *application* for a compulsory licence should not be admissible at any time after the date of publication of the patent application (about 18 months from the filing date of the patent application). The licence may not be granted by the Patent Office, but at least the issues can be aired, and strategic planning made easier for businesses.

Such amendments to the general compulsory licence provisions would however have to be undertaken at an international level, partly because it would require amendment of Art 5.A(4) of the Paris Convention, and partly because people are rarely interested only in obtaining licences in respect of one country, but would be looking for a licence covering the major industrial countries, so that a unilateral amendment to the UK law would not have much effect.

14. *(From Dr Jeremy Bray) Is the GATT/TRIPS Agreement likely to have any effect?*

Mr Hoptroff said that it would mainly affect developing countries. In relation to my last comment regarding compulsory licensing, however, I think that it contains one or two retrograde provisions in the relevant section (Art 31), particularly in subsection (f) which specifies that any use of the invention under a compulsory licence shall be authorized predominantly for the supply of the domestic market of the member authorising such use.

B. *Arising out of the questions to myself and Tim Roberts*

1. *(From Dr Alan Williams—I think) Is it true that the USA Patent Office allows more and more to be patented, while the UK Patent Office allows less and less?*

I have not come across this notion before, and I am not sure where it would have come from. Perhaps it is the fact that the US Patent law does not contain explicit exceptions to patentability of the kind that we have in Europe. In practice, however, there is very little difference between USA and Europe as to what can be patented. Even US patent claims directed to methods of therapeutic treatment (something specifically excluded in Europe) are likely to be interpreted in much the same manner (ie have much the same practical effect) as the differently worded European counterpart patents.

As regards the patentability of gene sequences per se, there is very little to go on in the way of granted patents, from which one can form a view as to comparative trends one way or the other. Examples will doubtless emerge over the coming years. However, the *more* stringent "utility" requirement in USA may in fact make gene sequences more difficult to patent there than in Europe.

2. *(From William Powell) Are the Patent Offices too lax in their standards of what is patentable?*

Some users say so. Others say the contrary. It is inevitably a balance, having regard to the needs of industry and the public interest.

I am not convinced that the overall standard is seriously wrong. However, the standard does seem on occasions (ie in particular cases) to have drifted badly from what is reasonable; for example the notorious case in USA, where a patent was granted which effectively monopolises *all* genetic engineering of the cotton plant.

To my mind, what is important is that the validity of patents should be easily challenged, and on *all* grounds which are examined before grant. As already mentioned, undue claim breadth is excluded as such from post-grant challenge.

Furthermore, it is *extremely* difficult, not to say costly, to challenge the validity of a US patent. If there is one thing more than another which would be useful in harmonising the idiosynchratic US patent law and practice with that of the rest of the world, it would be for the US patent law to provide for post-grant opposition proceedings before the US Patent Office (and also early publication of pending patent applications, and public inspection of the Patent Office files of pending applications).

3. *(From Dr Alan Williams) Do we not need a different approach to patenting in the field of human genetics than eg plant, or even animal, genetics?*

It is not clear to me why this should be so. Merely because the subject matter concerns humans ought not to make patenting fundamentally different. After all, the overwhelming bulk of the pharmaceutical industry is concerned with the treatment of humans, and yet it is not being suggested (at least not by Dr Williams, I presume) that one should have a fundamentally different and more restricted approach to patentability in that area. (There are specific restrictions, in that one cannot patent methods of therapy, diagnosis or surgery practised *on* the human or animal body, but that is not really relevant to our consideration here.)

Of course, human genes are in a sense the very "essence" of our being; but this sort of metaphysical thinking should not cloud our objectivity in assessing the very mundane and practical question of patentability. As already remarked; a patent is merely a legal right to stop others from carrying out commercially that which the patentee has invented. That may be the manufacture of DNA corresponding to part of a human gene; it may be the use of that DNA to manufacture the encoded protein; it may be the use of that DNA to provide a form of gene therapy. Such practical and commercial applications as these are the typical subject matter of the patent monopoly, and are not things which the individual human, in whose body the gene occurs, would do himself. Therefore the patent does not deprive ordinary humans of their existing rights or freedoms.

As to whether the patent inhibits scientific freedom or commercial activity; it certainly does the latter, which is the very essence of a patent, but it does not prevent non-commercial scientific research.

In short, I do not see that patenting of human genes in relation to their practical use for the benefit of mankind (eg in diagnosis or therapy) should be treated any differently from the patenting of other diagnostic or therapeutic subject matter which is not based on genes and which have been patented for many years without undue controversy.

Insofar as any of the practical uses of the gene sequence information may be seen to be socially undesirable, then that should be the subject of more general regulatory legislation (see the earlier remarks on "ethics" in patent law).

C. Supplementary Questions from the Clerk of the Committee—letter of 9 February 1995

What are the "modest" costs of challenging a patent in the courts?

Did I really say that?

Just a bit of backgound: the validity of a UK patent can be challenged in proceedings before the High Court, the Patents County Court or the Patent Office; while a European Patent (EP) can be challenged as a whole before the EPO (within nine months following grant) or before the national courts or patent offices (with only national effect).

An EP has to be regarded as the same as a UK national patent insofar as it designates this country (which is usually the case).

The cost of challenge varies a good deal according to the forum chosen. The UK High Court is very expensive, the Patents County Court *ought* to be less so, and the Patent Office perhaps least of all. The cost of challenging at the EPO (so-called "opposition") is probably somewhat similar to challenge before the UK Patent Office.

The costs vary a great deal, depending on the complexity of the case; and unfortunately, perhaps, biotechnology inventions are among the most complex; or perhaps it seems so because most of the clients for whom I act in such challenges are big companies who are prepared to spend a lot to mount the most comprehensive challenge.

Thus, an EP opposition in this field might cost the client in the order of £50,000. If that seems less than modest, a High Court action would be at least 10 times as much, and the losing party would have to pay a large part of the winning party's costs (which is not the case at the EPO).

If I were asked by a "small" client to oppose an EP which was seriously inconveniencing him; I would try and dissuade him unless I thought that there was a strong case, and then I would apply the arguments most cost-effectively rather than most comprehensively. I would estimate that an effective opposition under those circumstances could be carried out for around £10,000.

That may still seem less than "modest", but it is comparable with the cost of getting the European patent in the first place.

Also, it has to be remembered that a patent is essentially a *commercial* legal instrument, and not generally applicable to the activities of private individuals (at least when it comes to challenging the validity of a patent). What may seem an exorbitant cost to an individual may be relatively insignificant in the context of a commercial enterprise.

Finally, if an individual (scientist, for example) has relevant information (eg a prior art document) which he thinks casts doubt on the patentability of a pending patent application in Europe, he can file that information himself at the patent office in connection with that pending application, and the examiner will take it into account during the examination. This "slipping a note under the headmaster's door" does not cost the individual anything.

Memorandum submitted by T W Roberts on behalf of the Chartered Institute of Patent Agents (CIPA) following oral evidence given on 8th February. (17.3.95)

PATENTING HUMAN GENES

1. It is understood that the Committee is considering whether to recommend that genes (or human genes) should be unpatentable. CIPA believes that patents should continue to be granted on human gene sequence inventions, for the reasons set out below.

2. CIPA's view is that, in general, anything which is new, inventive and industrially applicable should be patentable. Special exceptions are undesirable, without clear cause. In order to patent a gene, as a minimum its sequence must be newly provided. Then there must be a practical application established for it. Finally, the applicant for a patent needs to show that the necessary element of invention is present. If possession of the isolated gene solves a significant technical problem, that will be strong evidence that an invention has been made. If the problem can be solved by routine methods which it would be natural to apply, typically no invention has been made, and no patent should be granted. This follows from existing law and practice it does not require special legislation.

3. For example, Professor Bobrow refers to cases in which genes are identified and cloned "by three or five groups within a matter of weeks" (Q18). In such a case it seems likely that the gene would be a recognised target with an obvious use, and could be isolated by known methods—this would make a strong case (in the absence of special circumstances) that no patent should be granted.

4. However, to make a rule that a new isolated gene can under no circumstances be claimed as an invention is, in our view, without justification. Like all such special exceptions, it will lead to fierce (and ultimately futile) debate about what is excluded. Will functional but non-coding parts of genes (such as promoters) be patentable? What about sequences closely similar to, but not identical with, those in nature? What about combinations of natural genes, or parts of them (for example, cDNAs) which code for useful therapeutic proteins (eg tPA derived proteins which are fragments or mutated forms of the human protein)? All of these might be excluded from patentability (although new, inventive, and perhaps exceptionally useful—providing lifesaving drugs, for example) by a rule which says genes may not be protected. The resulting uncertainty will be as damaging as the loss of protection.

5. Part of the objection to patenting gene sequences derives from the view that, being pre-existent, they cannot be inventive. But in many cases there may have been no previous knowledge of the function, or even existence, of the gene; and the fact of the matter is that even where a gene is known to exist, it may be difficult, and require invention, to locate, isolate and sequence it, thereby providing it in a useable form. To deny patent protection in these circumstances is like denying copyright protection to the stonemason on the grounds that the human figure he creates was always present in the block of stone—it was simply a matter of chipping it out.

6. It is also objected that to establish the sequence of a gene is a "mere discovery". The objection to patenting a discovery is that it enables the discoverer to monopolise what is already available—to claim an old thing because something new has been found out about it. That is fundamentally unacceptable in a patent system. Patenting an isolated gene, however, gives no rights over the original unisolated gene in its natural state; only over the newly isolated gene and material derived from it. It has long been the practice to grant patents for materials newly isolated from natural sources.

7. The objectives of the Committee are, we believe:

To make research easier;

To make medical treatment cheaper;

To protect the human body from inappropriate commercial exploitation.

It is contended that the proposed change will contribute very little towards these important objectives; but will have the following undesired side-effects:

To delay or prevent introduction of important new cures;

To confuse the law in this area, to the disadvantage of industry;

To bring the UK into conflict with important treaty obligations.

8. It was a view of several witnesses that only the gene sequence should be unpatentable: they did not object to patenting uses [see for example Professor Borbrow, Q20. " . . . I am certainly not against patenting of processes, diagnostic procedures, therapeutic modalities or any sort of derivative use.". Mr Kent, Q265, "If

you need a mechanism to get it from the test bench . . . into the recipient . . . the processes . . . that is all inventive stuff and should potentially be patentable."]

9. These witnesses have not appreciated what the current European law is [I am at fault in not having made this clear [Q385, 386)]. In the USA, as was said (Q385), all subject-matter is in principle patentable, except human beings. This includes processes for therapeutic treatment of the human body. Such processes are NOT however patentable in Europe (EPC 52.4). Products for use in such processes are patentable, at present. But if the Committee's proposal is followed through, the discoverer of a new gene might be unable, in Europe, to protect either the product itself, or the process of using it. This would remove incentive from commercial companies to research in these areas, or even to develop the products of others' research (including academic research). Thus the proposed amendment would have a severely damaging effect. Moreover, the European pharmaceutical industry, unable to obtain such protection in its home market, would feel at a particular disadvantage opposite US and Japan.

Would the amendment make research easier?

10. Professor Bobrow says (Q18) that gene research is intensely collaborative, and that the availability of patenting can only slow down such collaboration. As genes are patentable at present, it appears that he believes that denial of patentability would speed research up. That view must be given weight, even though it is hypothetical. A contrasting view (also hypothetical) is that patenting increases availability of research material, at least from sources in the private sector. The possibility of patenting allows those in the private sector to distribute more widely materials that otherwise would be kept as trade secrets. In any case, would any speeding up of research compensate for the inevitable slowing down of commercial development and consequent widespread use?

Would the amendment make treatment cheaper?

11. This would undoubtedly be the effect on existing gene-based products (but only provided the amendment was retrospective—a Draconian step). But this would not justify the loss of new products. Without patents, the investor cannot recover the cost of innovative research and development—so he stops doing it, and simply waits to copy the successes of others—which become much rarer.This is to kill the goose that lays the golden eggs–sufferers from diseases as yet without remedy will be deprived of their best chance of a cure.

Is it unethical to patent human genes?

This question is discussed in the Appendix. In general, CIPA as a professional body does not feel entitled to give a view on ethical questions.

Will cures be delayed?

12. Whatever the exact legal effect (see below) commercial organisations, and those who fund them, will believe that protection for their research investment is reduced, and will redirect their efforts. This will reduce the rate at which innovations are introduced. Given the pressing need for such innovations (of which a hint is given by the price they can command in the market) such reduction is unacceptable.

13. New drugs in this country are almost invariably introduced by research-based pharmaceutical companies. The cost of development of a new drug is enormous—an average figure of £200 million is currently quoted by the Association of the British Pharmaceutical Industry. Most of this goes to prove that the product is safe and effective. This cost has to be recovered in the price of the drug—this is why new drugs are so expensive. Innovators cannot hope to compete with copiers whose costs are a fraction of theirs. For this reason the companies place major importance on the availability of patent protection for their innovations. If this is not available, they will not develop for this market—or only in special circumstances. Manufacture will be left to "generic" manufacturers, who will introduce only those products which have proved a success elsewhere. The importance of drug patent protection has been recently recognised throughout Europe by introduction of short extensions of patent term to compensate for regulatory delays. Without secure protection, some products will be introduced late, and others will not be produced at all. The benefits of these products—the economy, and, more importantly, to patients—will be delayed or lost.

Will the law be clear?

14. No. See paragraph 4. The law provides a workable framework at present, and any major perturbation will stir up the mud and make the system uncertain for years to come. This damages confidence, and diverts energies and resources unproductively.

How would our international position be affected?

15. The proposed ban is contrary to international agreements to which the UK is party. The European Patent Convention (formed by Switzerland and all EU nations except Finland) provides a complete code as to what is patentable. The European Patent Office has determined that this code permits the patenting of genes. The ban will equally be contrary to the intellectual property provisions of the World Trade Organisation (TRIPs). Article 27 of TRIPS provides that patents are to be available in all technical fields without discrimination. Exceptions are made for plants and animals, but not microbiological processes or products. TRIPS provides no exception for gene patents, and other developed country members of the WTO are likely to react strongly to any proposal in breach of these provisions. The UK needs to set an example in implementing TRIPS, not to seek to derogate from it.

What other objections have been raised to patenting genes?

16. Fears are expressed (Professor Bobrow, Q18) that the patent-holder will be able to suppress the invention, or certain uses of it. Patent attorneys know from experience that use of patents to suppress inventions is a myth. Patenting requires publication. A patent holder who is not interested in developing a particular market will normally be willing to grant a licence. Unreasonable refusal of a licence makes the patentee open to an application for a compulsory licence, terms to be fixed by the Comptroller of Patents. Failure to develop an invention is much more likely to be due to lack of patent protection (see 13 above).

17. Apparently, no specific evidence has been given to the Committee of circumstances in which a patent has hindered research. Professor Williams wrote a letter to The Times (19 November 1994) alleging that Chiron were using their patent to control research on hepatitis C. A reply on behalf of Chiron (9 December 1994) claimed that, since grant of the patent, over 4,000 scientific papers have been published and more than 350 patents filed by a wide range of organisations: and that Chiron had licensed three UK diagnostic companies to supply kits. If there are more relevant examples, CIPA is not aware of them.

18. Professor Bobrow and Mr Kent both object to gene patents on account of their scope. Professor Bobrow says (Q18) that the patent gives ". . . an absolute monopoly. There is no other way out of it." Mr Kent says (Q262) that the claim is ". . . controlling an outcome." It is certainly a reasonable objection to a claim that it covers all possible ways of solving a recognised problem. Patents are granted for solutions, not problems. But is it really true that the monopoly given by a claim to a gene cannot be avoided? A claim to a gene sequence for producing an enzyme may, sometimes, be avoided by a substantially different sequence producing a similar but not identical enzyme (perhaps one that is more effective). A claim to a gene useful as a marker for a genetic disease may, perhaps, be avoided by using a sequence not forming part of the gene but very close to it in the genome. There are other possibilities. It is often difficult to avoid a claim to a gene defined in terms of its function ("coding for enzyme X" for example—and an added difficulty is that enzymes are generally named by function, so that—for example—"chitinase" simply means an enzyme that breaks down chitin). But it is not yet settled that it is proper to claim a gene using such a broad definition. The courts will make such decisions case-by-case. Even in USA (generally seen as the country most sympathetic to biotech patents) the Appeals Court has cast doubt on the validity of claims so framed. Provided claims are not too broad (as claims to all ways of solving a problem clearly are) we think that they can stimulate useful new approaches by inventors seeking alternative solutions.

19. Finally, we note that Professor Bobrow finds an unexplained difference between US and UK entrepreneurs in this area. We believe part of this can be accounted for by the greater confidence of the US innovator that he will have effective patent protection.

APPENDIX

ETHICS—A PERSONAL VIEW

Several witnesses have given evidence to the Committee that they think it immoral to own human genes, because they are parts of the human body.

Questions of morals are for everyone, not for specialists who work in the area. But specialists are entitled to ask what moral principles are being invoked, and whether they make sense in the context. Most people would readily agree that a third party should not have rights of ownership over an organ in a person's body. But a patent does not give this. The patent gives rights only over what is new, eg, an isolated gene. It cannot give rights over the starting-point for the invention, eg, the natural gene in the form in which it previously existed in the human body. Further, the isolated gene is a copy of what was in the human body, not the original—more like a fingerprint than a finger. The human body still retains everything it had before. The patent gives rights only over industrially applicable uses of the isolated gene.

None of this is to justify taking samples from people for one purpose and using them for another. It might be entirely reasonable to require that those who take human samples should do so with specific permission, and not use them for new purposes without further permission. But it is quite unnecessary to have any blanket

ban on patenting of materials derived from human samples. As with photographs of people, the circumstances in which they are taken, and the use made of them, may be controlled to take account of the rights of the subjects (eg, to privacy). But, just as the copyright in the photograph belongs to the photographer, so the intellectual property in the isolated gene belongs to its inventor.

A stronger case could perhaps be made that it is unethical to forbid patenting of human genes. Respect for human dignity should surely discourage putting obstacles in the way of developing products to relieve human distress.

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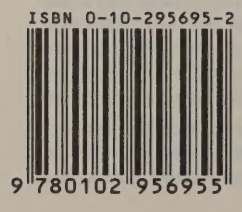

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